UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

ex rel. ROBERT E. MANCHESTER et. al.,
PLAINTIFFS,

Case no. 5:18-cv-73

v.

PURDUE PHARMA, L.P. et al.,
McKESSON CORPORATION,
CARDINAL HEALTH INC., and
AMERISOURCE CORPORATION,
DEFENDANTS

COMPLAINT AND DEMAND FOR TRIAL BY JURY

Qui Tam Plaintiff Robert E. Manchester, as Relator, brings this action on behalf of the United States of America, the State of Vermont and on behalf of all similarly affected city, municipal or county "local governments" of the State of Vermont (collectively the "Vermont Local Government Plaintiffs") under the federal False Claims Act, 31 U.S.C. sections 3730 (c) (3) and 3732 (b) ("FFCA") and the State of Vermont False Claims Act, 32 Vt. Stat. Ann. sections 631 and 632 ("VFCA") against Defendants Purdue Pharma, L.P., et. al. ("PURDUE"), McKesson Corporation ("McKESSON"), Cardinal Health Inc. ("CARDINAL") and AmerisourceBergen Corporation ("ABC") as manufacturers and/or distributors and vendors of the ORIGINAL FORMULATION Class II opioid that was manufactured and sold by PURDUE PHARMA, L.P. during the years 1996 – 2010 (identified collectively as the "DEFENDANT

DISTRIBUTORS").

PRELIMINARY STATEMENT

PURDUE's original formulation of OxyContin triggered the onset of a national opioid epidemic and related health-care crisis. This epidemic began shortly after PURDUE began marketing and distributing its product in early 1996. It expanded in scope for more than a decade until PURDUE was able to replace that product with a revised formulation. This occurred about three years after the Company and several of its officers plead guilty to criminal misbranding.

In the 2007 plea bargain PURDUE struck with the United States Department of Justice, it admitted that it had marketed and promoted the ORIGINAL FORMULATION of its product contrary to the limitations set forth in the labeling initially approved by the Federal Food and Drug Administration ("FDA"). This plea bargain, for criminal misbranding (a felony conviction in violation of 21 U.S.C.A. sections 331(a) and 333 (a) (2), constituted a fraud perpetrated upon those physicians and patients who had relied upon the willful misrepresentations made by PURDUE in violation of the labelling restrictions the FDA had imposed when it approved PURUDE's new drug application ("NDA 20- 553") in 1995.

This plea bargain, however, did not address an entirely separate fraud that was entirely unrelated to PURDUE's initial or subsequent labeling.

That fraud involved two separate but related acts on the part of each Defendant[1] that

[1] PURDUE as manufacturer and "applicant" of NDA 20 – 553 was required to comply with the mandatory reporting requirements of 21 C.F.R. section 314.80 (a). In addition, as "registrant" of a Class II opioid pharmaceutical product [definition includes all "manufacturers, distributors and dispensers" of controlled substances] PURDUE was

involved a willful and knowing conspiracy to violate the federal and State of Vermont False Claims Acts:

First: Willful failure of PURDUE to Comply with Mandatory Reporting Obligations of 21 CFR 314.80

PURDUE'S intentional failure to report to the FDA "any significant failure of expected pharmaceutical action", a mandatory reporting obligation set forth in 21 CFR 314.80, which PURDUE as manufacturer and "applicant"[2] of a pharmaceutical product was required to meet as a condition imposed by the FDA in its 1995 approval of NDA 20 – 553. See 57 FR 17950, April 28, 1992 amendment to section 314.80[3] [1992 21 CFR 314.80].

That fraud, perpetrated on the FDA, prevented its doctors and research scientists from carrying out their responsibility to evaluate whether the data contained in PURDUE'S adverse reaction reports and related materials demonstrated unexpected "frequency" of addiction and overdose complaints sufficient to warrant a post-market risk-benefit analysis of the product

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required to "provide effective controls and procedures to guard against the theft or diversion [of such products]. Cf. ". Masters Pharm., Inc. v. DEA, 861 F. 3d 211 – 212 (D.C. Cir. 2017). See n. 5 – 6 supra. PURDUE and the DEFENDANT DISTRIBUTORS, each as "registrant", were required as "distributors and dispensers" to act immediately to report to "DEA all orders of unusual size, frequency or pattern ... that gave rise to the suspicion that the customer was diverting controlled substances" (Masters Pharm. 963 F. 3d at 222- 223. See n. 5 infra.

[2] See n. 1 supra.

[3] In 1985 the FDA proposed certain "New Drug and Antibiotic Regulations" (see 50 FR 7452, date February 22, 1985). On April 28, 1992, section 314.80 of these regulations was revised, as follows: "FDA proposed several changes to 21 CFR 314.80 [including the following to Section 314.80(a)] ... under the existing regulation defined an "adverse drug experience," in part, as "any significant failure of expected pharmaceutical action." The proposed rule would delete the adjective "significant" from this definition and, as a result, require reporting of "any failure of expected pharmaceutical action." The proposed rule also would require applicants to review all adverse drug experience information "obtained or otherwise received by the applicant from any source, foreign or domestic," and to review periodically the frequency of reports of adverse drug experiences "that are both serious and expected ... and report any significant increase in frequency as soon as possible". This regulation was in force in December 1995 when PURDUE received approval from the FDA of NDA 20 – 553. See paragraph 14 infra.

and possible suspension or restriction of further sales until that analysis could be performed and the continuing safety of the product could be determined[4].

Beginning in 2002, if not before, PURDUE had actual knowledge that its ORIGINAL FORMULATION was subject to wide-spread illicit diversion and abuse and that several hundred or more of its prescribing physicians were then acting recklessly and illegally prescribing the ORIGINAL FORMULATION for distribution to addicts or their suppliers ("Suspect Physicians").

Relator asserts that beginning in 2002 if not before PURDUE, intentionally and repeatedly violated 1992 21 CFR 314.80 once it "developed certain internal criteria" it used to create 'a ... confidential roster [of Suspect Physicians]" (see paragraphs 41.A – 41.C). During such time PURDUE was required to comply with this regulation by the terms imposed by the FDA in its approval of NDA 20-553. The regulation then in effect required PURDUE to report "any failure of expected pharmacological action" to the FDA (see 57 FR 17950, eff. date April 28, 1992) and to "provide a complete picture of adverse drug experiences, rather than selected reports that would improve the agency's ability to determine whether it should take regulatory action" (Id. comment to section 314.80).

The term "significant failure", as used by the FDA, was intended to include "manufacturing problems or batch problems" (see FDA Comment # 73, 50 FR 7452, eff. date February 22, 1985). The term "Adverse drug experience" was defined by the FDA to mean: "Any

[4] See, e.g., Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466 (2013), n. 10: "See Government Accountability Office, Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process 10 (GAO-06-402, [***72] 2006 (noting that 10 drugs were voluntarily withdrawn by the manufacturer for safety reasons between 2002 and 2006); Wysowski & Swartz, Adverse Drug Event Surveillance and Drug Withdrawals in the United States, 1969 – 2002, 165 Archives Internal Med. 1363 (2005) (noting that more than 75 drugs and drug products were withdrawn from the market for safety reasons between 1969 and 2002).

adverse event associated with the use of a drug in humans ... including ... an adverse event occurring from **drug abuse (emphasis added)** [and] an adverse event occurring from drug withdrawal" (see 1985 21 CFR 314.80 (a). In 1985 the FDA defined the term "serious" for the purposes "of the final rule [to mean] an adverse drug experience that is life threatening ... [including] ... overdose [that] is always to be considered serious." (Id., 50 FR 7452, Comment 71.c).

Notwithstanding such knowledge and related information, contained in its internal records, PURDUE failed to disclose that information to the FDA in willful violation of 1992 21 CFR 314.80 (reporting obligation required drug manufacturer to report all drug overdoses, a type of "adverse drug reaction" deemed "serious" by the FDA) and "any failure [specifically including "manufacturing problem"] of a drug product to produce its expected pharmacological action". Additionally, PURDUE made the decision to continue to sell or distribute its ORIGINAL FORMULATION to pharmacies for the purpose of filling prescriptions of its Class II opioid product to medical doctors who it then knew were making "reckless" or "atypical" prescriptions to illicit drug users and their suppliers, and did so without making such knowledge known to any federal or state governmental agency, including but not limited to the FDA or DEA or any other federal or state governmental agency .

Further, PURDUE failed to disclose to the FDA the decision it had earlier made in 2002 to develop "a tablet which would be difficult to crush or syringe" and later efforts to purchase from its competitors within the pharmaceutical industry licensing rights that would enable PURDUE to incorporate in its product a suitable "controlled release-mechanism" that would have "the necessary physical structure and chemical composition ("hardness") required to prevent 'rampant abuse of the drug'" (see paragraph 15 infra). In 2002, if not before,

PURDUE knew that its ORIGINAL FORMULATION lacked suitable hardness because its method of construction (involving wet granulation and direct compression methods; see paragraph 45 infra) was inadequate as a means to prevent "parenteral, nasal and/or oral abuse ... [of the product and its] abuse potential" (see paragraph 26 infra).

In 1995 PURDUE had represented to the FDA in NDA 20- 553 that the "[d]elayed absorption [of its ORIGINAL FORMULATION] is believed to reduce the abuse liability of a drug" (paragraph 22 infra) but did not provide the FDA with any clinical data which demonstrated that its ORIGINAL FORMULATION "was less addictive, less subject to abuse or other diversion, or less likely to cause tolerance and withdrawal than other medications" (paragraph 23 infra). The FDA accepted that representation and neither it nor PURDUE then considered" whether crushing of the ORIGINAL FORMULATION tablet would become wide-spread and lead to a high level of abuse once addicts and their suppliers became aware that the tablet was readily susceptible to crushing for purposes of illegal injection or snorting" (paragraph 25 infra).

Almost twelve years later when it pled guilty to criminal misbranding, PURDUE failed to disclose to the Department of Justice or the FDA or any other federal or state governmental agency that its INTERNAL SALES records, which it had begun to keep in 2002 or before, contained information from which PURDUE could identify "physicians suspected of recklessly prescribing to addicts or dealers" (see paragraph 41.A infra) ("Suspect Physicians"). Such failure constitutes a willful failure on the part of PURDUE to comply with the mandatory reporting obligations set forth in 21 CFR 314.80. Such failure was compounded by PURDUE's ongoing decision to continue to sell and distribute its ORIGINAL FORMULATION to its "Suspect Physicians" who PURDUE knew had written and were continuing to write prescriptions to

abusers and their illicit suppliers and to make related decisions not to comply with the mandatory reporting obligations set forth in both the 2007 Corporate Integrity Agreement between PURDUE and the Office of Inspector General (see paragraph 41. F infra) and the various Consent Judgments or Settlement Agreements PURDUE negotiated with a majority of states in 2007 (see paragraph 41.D infra for discussion of terms of Vermont Consent Judgment).

Second: Willful Failure of Defendant Distributors to Comply with Mandatory Reporting Obligations of 21 C.F.R. 1301.77

The DEFENDANT DISTRIBUTORS as "registrants"[5] acted on behalf of PURDUE to distribute vast quantities of ORIGINAL OXYCONTIN during the years 1996 – 2010. During those years McKESSON, CARDINAL and ABC undertook to distribute in interstate commerce the ORIGINAL OXYCONTIN product for purposes of sale to drug stores and pharmacies in all 50 US States and Territories. Such distribution of a Class II opioid product was subject to and regulated by the 1970 Controlled Substances Act (21 U.S.C. section 8801 et seq.) and the mandatory reporting obligations contained in that Act which required each DEFENDANT DISTRIBUTOR as a "wholesale distributor" of controlled substances to register with the U.S. Drug Enforcement Administration ("DEA") for approval as a "vendor" of controlled substances under 21 C.F.R. sections 821 – 830 **and** "to report to [the] DEA all suspicious orders[6] for

[5] See n. 1 supra.

[6] The term "suspicious orders" is defined by 21 C.F.R. section 1307.71 (a) as "includ[ing] orders of an unusual size, pattern, or frequency" (Master's Pharm. supra, 861 F. 3d at 221. HN8). The court held that 21 CFR section 1301.74 "does not exhaustively list characteristics that might make a retail pharmacy's order for large quantities of controlled substances 'suspicious' (citation omitted) and cited with approval the DEA administrative decision in Southwood Pharmaceuticals, Inc.; Revocation of Registration, 72 FR 36487, dated July 3, 2007, at pp 36,487 and

controlled substances and to take other precautions[7] to ensure that those medications substances would not be diverted into illegal schemes". Masters Pharm., Inc. v. DEA, 861 F. 3d 211 – 212 (D.C. Cir. 2017). See 21 C.F.R. section 1301.77, discussed in n. 6 – 8 infra.

Relator asserts that in 2002 if not before the DEFENDANT DISTRIBUTORS knew or had the opportunity to know[8] that the ORIGINAL OXYCONTIN product each had and continued to distribute as vendor to its US drug store and pharmacy customers was subject to ongoing wide-spread illicit diversion and abuse and that many of its retail customers had filled prescriptions for persons who were addicts or suppliers of addicts. See infra paragraphs 41.A – 41.F. ("Suspect Pharmacies").

36, 501-02 (internet pharmacy's orders were "suspicious because the pharmacy was buying an unusual mix of controlled and non-controlled substances ... which were not consistent with what legitimate pharmacies typically ordered").

[7] 21 CFR section 1301.71 imposes upon all "registrants" (that is, all manufacturers, distributors and dispensers of controlled substances) the mandatory obligation to "provide effective controls and procedures to guard against theft or diversion of controlled substances". See Master's Pharm. supra, 861 F. 3d at 222- 223 (distributor must act to immediately report to "DEA all orders of an unusual size, frequency, or pattern [unless it] chooses to shoulder the burden of dispelling all of the 'red flags' that gave rise to the suspicion that the customer was diverting controlled substances" (citation omitted). The DEA "security requirement at the heart of the case mandates that distributors design and operate a system to identify suspicious orders of controlled substances and report those orders to the DEA" (interior quotation marks deleted) (Masters Pharm., 851 F. 3d at 213 – 214). The mandatory reporting requirement was enacted "so that DEA investigators in the field can aggregate reports from every point along the legally regulated supply chain and use the information to ferret out potential illegal activity" (interior quotation marks and citations omitted) (Id., 861 F. 3df at 212). See Federal Register, vol. 80 no. 178: DEA Decision and Order dated September 15, 2015 in re Masters Pharmaceuticals, Inc. docket no. 13 – 38 at pp 55500 – 55501 for Summary of findings of ongoing violations of 21 CFR 1301.74(b), such as rarely investigating any order of suspicious size, whether by "contacting the pharmacy and obtaining an explanation for such order [or by] independently verifying that explanation; or filling an order "without obtaining an explanation from the pharmacy; or by "entirely" deleting an order "as if it had never existed rather than report it as suspicious" or by editing and order and "reducing its size so that the pharmacy's orders did not place it over its CSL [Controlled Substance Limit]".

[8] Among other things, the DEA regulations prohibit the filling of a prescription to a drug store or pharmacy where that order was deemed "suspicious". Under that circumstance, the distributor could decide not to fill the order or to decide to make an immediate report to the DEA of any order of "unusual size, frequency, or pattern" or could instead require the drug store or pharmacy to produce its "actual dispensing records". Masters Pharm., 861 F. 3d at 222 – 223 (citation omitted).

Relator further asserts that beginning in 2002 if not before such DISTRIBUTORS were required to maintain certain internal records that contained their sales and distribution data from which they could determine which of their retail drug store and pharmacy customers ("Suspect Pharmacies") had undertaken to dispense ORIGINAL OXYCONTIN to persons then engaged in illicit diversion through criminal schemes related to the making of false claims of "medical necessity", a necessary first-step toward the submission of each such false claims to Medicaid for payment, and that such knowledge on the part of the DEFENDANT DISTRIBUTORS satisfies the definition of "knowing" or "knowingly" set forth in 31 U.S.C. section 3729 (b), subparts (i) – (iii).

Relator asserts that as a proximate cause of such willful and knowing failures, PURDUE and each of the DRUG DISTRIBUTORS have knowingly made or caused to have been made multiple false records or statements material to the submission of numerous false or fraudulent claims for purposes of payment by Medicaid and have knowingly conspired with PURDUE to commit numerous violations of FFCA section 3729 (a) (1) and VFCA section 631(a) and should therefore be held liable for statutory damages each government has incurred under both the Federal and Vermont False Claims Act and under related provisions of the common law of the State of Vermont. These claims include two separate categories of damages: First, for statutory penalties and/or consequential damages for each false claim submitted to Medicaid for payment by physicians then engaged in an illegal enterprise to sell and distribute the ORIGINAL FORMULATION to addicts and their suppliers (see paragraphs 60 – 65 infra); and, Second, for consequential damages arising under state law claims of products liability, fraud, unjust enrichment, and consumer fraud related to the expenses paid by each

government as a part of its Substance Abuse and Addiction treatment programs, which expenditures were separate and apart from the health care services and products it paid as a part of its Medicaid program payments (see paragraphs 75, 83, 90.A, 95.A, 102.A, and 107.A. infra).

Lastly, Relator asserts that the applicable statutes of limitations should allow the UNITED STATES , the STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFFS to seek damages under the Federal and State of Vermont False Claims Acts (also cited as "FFCA" and "VFCA") for the period 2008 – 2018 (see paragraph 54. C infra) and under the common law of Vermont for the period 2002 – 2017 (see paragraph 54.D - 54.H infra). See paragraphs 54.I for discussion of Vermont "functional choice of law" rules.

JURISDICTION and VENUE

1. This is a civil action by Relator, acting on behalf of and in the name of the UNITED STATES and the STATE OF VERMONT and on behalf of the VERMONT LOCAL GOVERNMENT PLAINTIFFS against the DEFENDANT DISTRIBUTORS under FFCA sections 3729- 3733 and VFCA sections 630 – 631 and under the common law of the State of Vermont.

2. Relator has commenced this action by filing his complaint with the Court in camera and under seal as required by FFCA section 3730 (b) (2) and VFCA section 632 (b) (1). Relator served the Attorney Generals of the United States and the State of Vermont with a copy of the complaint and all material evidence and information used by Relator in preparing his complaint (see Summary of Attachments identifying documents cited in the complaint as well as copies of those documents in electronic format on an accompanying CD as required by FFCA section 3730 (b) (2) and VFCA section 632 (b)(3).

2. This Court has jurisdiction over the claims brought on behalf of the United States

pursuant to 28 U.S.C. sections 1331 and 1345, and FFCA sections section 3732(a).

3. This Court has jurisdiction over the statutory claims alleged herein brought on behalf of the State of Vermont and the Vermont LOCAL GOVERNMENT PLAINTIFFS under FFCA section 3732(b). In addition, the Court has supplemental jurisdiction over the common law claims brought on behalf of the UNITED STATES and the STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFFS under 28 U.S.C. section 1367. The VERMONT LOCAL GOVERNMENT PLAINTIFFS are those governmental entities within the definition of "State" set forth in VFCA section 4301(8).

Relator asserts standing on behalf of the UNITED STATES and the STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFFS to pursue all claims set forth in Counts Two – Eight of the complaint under the supplemental jurisdiction provisions of FFCA section 3732 (b). See Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765 (2000). HN 7 – 8.

4. Venue is appropriate in this district under 28 U.S.C. sections 1391(b)-(c) and 31 U.S.C. section 3732(a) because the DEFENDANT DISTRIBUTORS can be found, reside, or have transacted business in this judicial district, and acts proscribed by FFCA . section 3729 have been committed in this district.

THE PARTIES

5. Plaintiff/Relator Robert E. Manchester is a Vermont attorney and resident. Mr. Manchester has provided the United States and the State of Vermont with a copy of this Amended Complaint prior to filing as required by FFCA section 3730(b) and VFCA section 631.

6. The real parties in interest in this action are the United States of America, the State of Vermont, and each Vermont Local Government (that is, all counties and municipalities

and all other governmental entities "authorized or created by state law" (Cf. VFCA section 4301(8). Relator seeks damages on behalf of the United States, the State of Vermont and all Vermont Local Government Plaintiffs resulting from the submission of false claims by or on behalf of the Defendant Distributors to government health insurance programs under both FFCA section 3729 et seq., and VFCA section 630 et seq. and **seeks in addition** damages under common law principles of product liability, fraud, consumer fraud, and unjust enrichment for all actual and consequential damages sustained by each Vermont Local Government Plaintiff during the years 2002 – 2010 as a part of its spending on SUBSTANCE ABUSE and ADDICTION which was caused by and related to PURDUE's sales and distribution of ORIGINAL OXYCONTIN (see paragraph 76.A infra).

7. Defendants Purdue Pharma L.P. and Purdue Pharma Inc. are partnerships organized under the laws of Delaware with a principle place of business in Stamford, Connecticut. Defendant The Purdue Frederick Company, Inc. is a Delaware corporation with its principal place of business Stamford, Connecticut. Such Defendants are identified herein collectively as "PURDUE". Defendant McKESSON is a Delaware corporation with a principal place of business in San Francisco, CA. Defendant CARDINAL is an Ohio corporation with a principal place of business in Dublin, OH. Defendant ABC is a Delaware corporation with a principal place of business in Chesterbrook, PA.

8. PURDUE is a manufacturer and seller of pharmaceutical products, including the Class II opioid pain medication tablet that it markets and distributes for purposes of sale under the brand-name "OxyContin". During the period between approximately January 1, 1996 and Augsut 10, 2010 PURDUE manufactured and distributed for purposes of sale its ORIGINAL FORMULATION. From 1996 – 2010 Defendant Distributors acted as agents and distributors on behalf of PURDUE to distribute millions of tablets of ORIGINAL OXYCONTIN to retail pharmacies

and drug stores located in all US states and territories.

APPLICABLE FEDERAL AND STATE STATUTES

9. Plaintiffs the United States of America and the State of Vermont administer the federal Medicare and Medicaid programs, among others. On behalf of the United States and the State of Vermont, Relator seeks damages resulting from the submission of false claims to federal health insurance programs under the Federal and State of Vermont False Claims Acts (31 U.S.C. section 3729 et seq. and 32 Vt. Stat. Ann. section 630 et seq.).

10. Federal law and regulations, applicable to all participating states and territories, obligate any health care practitioner and any other provider of health care services that may be reimbursed by Medicaid or Medicare to assure, to the extent of their authority, that services or items ordered or provided to beneficiaries and recipients will be (1) provided only when medically necessary, (2) of a quality that meets professionally recognized health care standards, and (3) supported by evidence of medical necessity and quality. Cf. 42 U.S.C. section 1320c-5, 42 C.F.R. § 1004.10 and Vermont Medicaid Regulation 7104 [9]("MEDICAID MEDICAL NECESSITY STANDARDS"). In this action Plaintiffs the United States of America and the State of Vermont seek to recover, subject to 42 U.S.C. section 1396h, the money each expended pursuant to the federal medical assistance program.

11. Relator respectfully requests the United States, the State of Vermont and each City, County or Municipality of the State of Vermont to intervene as in this action under either FFCA section 3730(b) (2) (United States) or FFCA 3732 (b) (State of Vermont and local governments) (definition of "State" includes "State of Vermont, a county, a municipality or other subdivision thereof"; see VFCA section 630(8).

[9] See Attachment 24 for copy of Vermont Medicaid Rule 7104.

SUMMARY OF COMMON LAW
CLAIMS ASSERTED IN AMENDED COMPLAINT

12. This action asserts statutory and common law claims against Defendants PURDUE, McKESSON, CARDINAL and ABC, as manufacturer or as distributor and vendor of a Class II opioid brand-name pain-reliever prescription product known as "OxyContin". The action is brought on behalf of the UNITED STATES and the STATE OF VERMONT by a Relator under FFCA sections 3730 (c) (3) and 3732 (b) and on behalf of the STATE OF VERMONT and all VERMONT LOCAL GOVERNMENT INTERVENORS under VFCA sections 630 – 631. This action is also brought on behalf of the each Plaintiff as a common law qui tam action wherein the Relator asserts standing to act in parens patriae on behalf of each such Plaintiff and its citizens in a cost-recovery action that seeks to recover monies expended by each such Plaintiff to fund its Substance Abuse and Treatment Programs for persons of the United States who became addicted to OxyContin prior to 2010 when PURDUE discontinued further sale or distribution of the ORIGINAL FORMULATION of its product. See infra, COUNTS TWO – EIGHT infra.

13. The complaint contains eight separate counts: COUNT ONE seeks among other things a declaratory judgement that the various 2007 state and federal Settlement Agreements or Consent Judgments do not limit or preclude the claims for damages asserted by Relator on behalf of the STATE OF VERMONT or the UNITED STATES in COUNTS TWO – EIGHT of the complaint (see paragraphs 54.A – 54.B infra); COUNT TWO asserts a claim for liability and damages pursuant to the Federal and State of Vermont False Claims Act s(see paragraphs 55 – 66 infra); COUNT THREE asserts a claim of liability and damages for design defect pursuant to Restatement (Second) of Torts section 402A (see paragraphs 67 – 75 infra); COUNT FOUR asserts a claim of liability and request for injunctive relief and damages for unjust enrichment

(see paragraphs 77 – 84); COUNT FIVE asserts a claim of liability and request for injunctive relief and damages for consumer fraud against PURDUE under the Vermont Consumer Protection Act (see paragraphs 85 – 91 infra); COUNT SIX asserts a claim of liability and damages for consumer fraud against the DEFENDANT DISTRIBUTORS (see paragraphs 92 – 96 infra); COUNT SEVEN asserts a claim of liability and damages for common law fraud arising out of PURDUE's affirmative obligation as "registrant" [10] to comply with the mandatory reporting obligations set forth in 21 C.F.R. sections 821 - 830 (see paragraphs 97 – 103 infra); and COUNT EIGHT asserts a claim of liability and common law fraud arising out of each DEFENDANT DISTRIBUTOR'S affirmative obligation as "registrant" to comply with the mandatory reporting obligations set forth in 21 C.F.R. section 821 – 830 (see paragraphs 104 – 108 infra).

NATURE AND EXTENT OF OXYCONTIN EPIDEMIC

14. In December 1995 PURDUE obtained approval from the United States Food and Drug Administration ('FDA") of its New Drug Application no. 20-553 ("NDA 20-553") (Attachment 1). This approval authorized PURDUE to market and sells within this country a pharmaceutical product with the brand-name of "OxyContin". This product is a Schedule II controlled substance that presents a risk of opiate addiction to its users similar to morphine. This approval required PURDUE among other things to "comply with the requirements for an approved NDA set forth under [1992] 21C.F.R. section 314.80 and 314.81" (Att. 1, id., p 2).

15. In its ORIGINAL FORMULATION, the risk of addiction of OxyContin was made much worse by the defective design and construction of the tablet, which lacked the necessary physical structure and chemical composition ("hardness") required to prevent "rampant abuse

[10] See n. 6 – 8 infra.

of the drug". (In re OXYCONTIN ANTITRUST LITIGATION, 994 F. 2d 367, 414 (S.D. New York, January 14, 2014) (Attachment 2) (hereafter "'383 PATENT LITIGATION") (aff'd sub nom, In re Purdue Pharma, L.P. v. Epic Pharma, L.L.C., 811 F. 3d 1345 (Fed. Cir. 2016); and the concomitant development of an enormous country-wide illicit market for the product, a so-called "pill mill" operation whereby PURDUE through its distributors sold vast volumes of its ORIGINAL FORMULATION to illicit drug wholesalers and retailers and physicians who diverted that product for distribution to persons who had become addicted to opiates.

16. Illicit distribution of the ORIGINAL FORMULATION began shortly after initial distribution of the ORIGINAL FORMULATION in 1996 and then multiplied due to illegal distribution practices undertaken by PURDUE whereby it sold and distributed the ORIGINAL FORMULATION, and particularly its 80 mg tablet, to certain "pill mill operators" whom PURDUE had identified as early as 2002 if not before. The pill mill operation which PURDUE enabled became a multi-state operation and expanded exponentially each year from 1996 through 2010 when, for example, more than 1,000 Florida pain clinics purchased from PURDUE or its distributors more than 30 million doses of its ORIGINAL FORMULATION during the first six months of 2010 (a sales volume that constituted about 89% of PURDUE's total physician sales during that year) (New York Times article dated August 31, 2011). (Attachment 3).

17. PURDUE's "pill mill" operation continued after 2001 when PURDUE and its distributors McKESSON, CARDINAL and ABC had actual knowledge based upon their INTERNAL SALES AND DISTRIBUTION DATA that contained sales information involving (i) physician profiles and their prescribing practices **AND/OR** (ii) use and prescription patterns of each retail pharmacy and drug store that a significant number of their prescribing physicians and pharmacies were engaged in an illegal enterprise whereby they wrote prescription slips or purchased for illicit distribution vast quantities of the ORIGINAL FORMULATION for diversion to

persons then addicted to OxyContin or their suppliers. See paragraphs 41.A – 41.F infra.

18. Upon information and belief, vast quantities of the ORIGINAL OXYCONTIN that was sold to pill mills in other states were transported and then sold to persons then residing in Vermont and all US states and territories, including both persons addicted to the ORIGINAL FORMULATION and their suppliers.

19. Upon information and belief, during the years 1996 to 2001, PURDUE's total domestic sales of its ORIGINAL FORMULATION increased from about $44 million in sales (316,000 prescriptions) in 1996 to more than $2.5 billion in sales (14 million prescriptions) in 2001. After 2001, and until 2010 when PURDUE discontinued further distribution and sales of its ORIGINAL FORMULATION, product sales increased to more than $3.0 billion per year. During such time, also upon information and belief, the Defendant Distributors distributed for purposes of sale to retail pharmacies and drug stores located in all US states and territories at least 80% of PUDUE's ORIGNAL FORMULATION.

20. The design and manufacturing defect present in the ORIGINAL FORMULATION resulted in the onset of "a public health epidemic" that began soon after 1996 once patients discovered that the tablet, as constructed, could easily be crushed into power, with the result that the time-release mechanism of the tablet would be defeated and the full strength of the narcotic present within the tablet would be "released at once" into the blood stream of the user ('383 PATENT LITIGATION, 994 F. Supp. 2d at 414). (Id. Att. 2).

21. By 2001 thousands of Americans were addicted to the ORIGINAL FORMULATION of OXYCONTIN. They had become opiate addicts due to the defective design and construction of the tablet used in the ORIGINAL FORMULATION, a design that lacked the necessary hardness required to prevent intentional or inadvertent crushing of the tablet.

22. In 1995 when PURDUE obtained FDA approval of its OxyContin New Drug

Application (NDA 20-553) (id. Att. 1), it knew that the safety and effectiveness of its product was dependent upon the "Delayed absorption, as provided by [its] OxyContin tablets [which it stated] is believed to reduce the abuse liability of a drug". (2007 Agreed Statement of Facts, dated May 7, 2009 signed by United States and PURDUE, paragraph 18) ("2007 Agreed Statement") (Attachment 4). In addition, PURDUE then knew that "Oral oxycodone [a "semi-synthetic opioid agonist that has been available for clinical use since 1917"] is approximately twice as potent as oral morphine on a milligram basis". (Id., Att. 3, section 1.0. Background of Clinical Pharmacology and Biopharmaceutics Review, p 2).

23. In its 1995 NDA PURDUE did not provide the FDA with any clinical data which demonstrated that OxyContin "was less addictive, less subject to abuse or other diversion, or less likely to cause tolerance and withdrawal than other medications" (2007 Agreed Statement, paragraph 14. (Id. Att. 4).

24. On October 24, 1995 the FDA prepared an internal Medical Officer Review ("MOR") which stated in part: (i) that "The adverse experience profile of [OxyContin] is qualitatively similar to that of the parent drug, oxycodone" and (ii) that "Withdrawal is possible in patients who have their dosage abruptly reduced or discontinued" (2007 Agreed Statement, paragraphs 16 – 17). (Id. Att.4).

25. Prior to approval of NDA 20 – 553, neither PURDUE nor the FDA evaluated whether the tablet PURDUE intended to use as a pill matrix for its OxyContin product had sufficient physical or chemical hardness to prevent inadvertent or deliberate tampering of the tablet that would result in "the time release aspect of the formulation being destroyed and the opiate being released at once". (383 PATENT LITIGATION, 994 F. Supp. 2d at 414). (Id. Att. 2). Further, neither PURDUE nor the FDA considered whether one or more clinical studies were required in order to determine on an ongoing basis whether the ORIGINAL FORMULATION

would cause addiction or withdrawal symptoms in persons who were prescribed extended or long-term dosages of OxyContin for use on an out-patient basis or whether crushing of the ORIGINAL FORMULATION tablet would become wide-spread and lead to a high level of abuse once addicts and their illicit suppliers became aware that the tablet was readily susceptible to crushing for purposes of illegal injection or snorting.

26. In 1993 PURDUE filed a patent application for its product with the U.S. Patent Office. That application was granted on April 16, 1996 by patent no. 5,508,042 (hereafter "042 Patent") (Attachment 5). The expiration date for that patent was April 16, 2013. In its 042 PATENT, PURDUE claimed that the its proposed invention would provide a "controlled release composition" of its opioid medication "which acceptably controls pain over a substantially narrower daily dosage range" and "have substantially less inter-individual variation with regard to the dose of opioid analgesic required to control pain without unacceptable side effects". (Id. pp 1 – 2). PURDUE identified several types of coatings which it intended to use to provide a "controlled release mechanism" without also identifying any physical or chemical means intended to prevent "parenteral, nasal and/or oral abuse of [the] pharmaceutical active ingredients [of its product and its] abuse potential" (patent no. 8,114,383 B 2, filed on November 20, 2003 by Grunenthal GmbH ("383 Patent") p 2, claim No. 30 asserted by Grunenthal GmbH. (Attachment 6).

27. On November 29, 2007 PURDUE submitted to the FDA a New Drug Application that proposed a reformulated OxyContin. That NDA ("NDA 022272") was approved by the FDA on April 5, 2010 (id., Attachment 7). See also 383 PATENT LITIGATION, 994 F. 2d at 415. (Id. Att. 2). The reformulated product contained an "abuse-proof formulation", which PURDUE had developed using licensing rights it had obtained from a German company, Grunenthal GmbH. NDA 022272 required, among other things, that PURDUE "conduct epidemiological

studies to address whether the changes made to the OxyContin ... Controlled Release ... Tablets [the REVISED FORMULATION] ... actually result in a decrease in the risks of misuse and abuse, and their consequences". FDA NDA 022271 Approval Letter, dated April 5, 2010 p 2 Id. Att. 7).

28. The license PURDUE obtained from Grunenthal pertained to its November 20, 2003 patent application entitled: "ABUSE-PROOFED DOSAGE FORM". Grunenthal's patent application was granted on February 14, 2012 by patent no. 8,114,383 (the "383 Patent"). (Id., Att. 6). The expiration date for the 383 Patent is October 24, 2024.

29. By acquiring the 383 license, PURDUE acquired for the first time the ability to produce an "extremely hard" tablet sufficient in design and construction to prevent crushing or injecting of the product, a necessary first-step toward developing an abuse-proof tablet.

30. In 2011, if not before, PURDUE obtained a separate license from the Board of Regents of the University of Texas System ("Texas Board of Regents"). This license pertained to Patent no. 6,488,963 B1 (hereafter the "963 Patent") (Attachment 8). It enabled PURDUE to use the "hot-melt extrusion process" which had been developed by University of Texas scientists in 1995. In their March 2, 1999 patent application, the inventors claimed that their process was "particularly well suited for oral delivery ... [of] ... controlled-release pharmaceutical formulations". The hot-melt extrusion process was first published by the inventors on December 31, 1997 in their application filed with the World Intellectual Property Organization. See Attachment 9 (F Zhang, JW McGinity, "Properties of sustained-release tablets prepared by hot-melt extrusion" and list of related articles). See 383 PATENT LITIGATION, 994 F. Supp. 2d at 421. (Id. Att. 2). See also paragraphs 44 - 46 infra.

31. On April 16, 2013 the FDA withdrew its prior label issued for the ORIGINAL FORMULATION of OxyContin. On that date the FDA also approved a new label that allowed PURDUE to market its REVISED FORMULATION as having "abuse-deterrent properties".

(Attachment 10). See also 383 PATENT LITIGATION, 994 F. Supp. 2d at 415 (Id. Att. 2).

32. Upon information and belief, since April 2013 PURDUE has discontinued any further domestic marketing or sales of its ORIGINAL FORMULATION. Since then, it has distributed for purposes of sale within the United States only those tablets made using its REVISED FORMULATION, a product it continues to manufacture using technologies licensed to it under either the 383 or the 963 Patents or related patents later acquired by PURDUE. See complaint filed by PURDUE and Texas Board of Regents against TEVA PHARMACEUTICALS USA, INC., on April 3, 2014, in the Southern District of New York, docket no. 1:14 – cv – 02357 – SHS, paragraphs 13, 23 – 41 (summary of OxyContin patents issued to or licensed by PURDUE, as listed in the so-called Orange Book maintained by FDA) (Attachment 11).

33. Upon information and belief, on or about August 2010 PURDUE made the decision to terminate any further shipments of its ORIGINAL FORMULATION to its domestic distributors, including but not limited to Defendants McKESSON, CARDINAL and ABC.

34. Upon information and belief, when PURDUE decided to terminate any further shipments of its ORIGINAL FORMULATION, it also made the decision not to buy back or otherwise retrieve or prevent any further sales or distribution of its ORIGINAL FORMULATION to its domestic distributors or retailers or their health care provider customers.

35. From 1996 to 2001, PURDUE distributed vast quantities of its ORIGINAL FORMULATION. In 2001, for example, it sold 14 Million prescriptions and realized more than $2.5 Billion in product sales. During this five year period PURDUE did not voluntarily restrict its sales to ONLY those patients who had critical need of strong opiate medication and who could be prescribed that medication in hospital settings where the administration of the drug could be carefully monitored and controlled by pain medicine specialists. INSTEAD, PURDUE pursued an aggressive marketing campaign directed toward numerous diverse physician groups

particularly primary care physicians. In this effort PURDUE increased product sales of its ORIGINAL FORMULATION by more than 4400% from 1995 to 2001. This marketing effort resulted in a criminal conviction for product misbranding in 2007. See description of U.S. Department of Justice plea bargain, paragraph 47 - 49 infra.

36. On or before July 23, 2007, when the Hon. James P. Jones accepted the plea agreement reached by PURDUE and the United States Department of Justice (see United States v. Purdue Frederick Co., 495 F. Supp. 2d 569, 576 – 578 (W.D. Virginia 2009 (Attachment 12), PURDUE had actual knowledge of the addiction risk and propensity for abuse by users of its ORIGINAL FORMULATION which contained "several doses of oxycodone – a powerful opiate – into a single tablet that released the oxycodone over time [and further knew that its product] was subject to tampering ... because abusers could crush the tablets easily into powder [with the result that] the time release aspect of the formulation [would be] destroyed and the opiate [would be] released at once". (383 LITIGATION, 994 F. Supp. 2d at 414. (Id. Att. 2). Further, PURDUE then knew or should have known that large quantities of its ORIGINAL FORMULATION, particularly its 80 mg tablet, had been and were continuing to be prescribed illegally by physicians for sale to and use by addicts and their suppliers.

A. Notwithstanding such knowledge, PURDUE undertook to continue unrestricted marketing and distribution for the purpose of sales of its ORIGINAL FORMULATION without first developing, or acquiring licensing rights from third-parties of, a drug-abuse deterrent technology which would prevent, or at least substantially reduce, the addiction risk and propensity for abuse of its ORIGINAL FORMULATION.

B. Furthermore, at all times material between 2001 -2007, PURDUE had actual

knowledge from its INTERNAL SALES DATA that several hundred or more of its prescribing physicians were acting "recklessly" and illegally prescribing the ORIGINAL OXYCONTIN product, particularly the 80 mg tablet, for distribution to addicts or their suppliers.

C. In 1995 when PURDUE obtained approval by the FDA of its NDA 20-553 (Att. 1) it was unaware that chemical and physical design and construction of its ORIGINAL FORMULATION would create a "public health epidemic" and result in wide-spread illicit sale and diversion to addicts and their suppliers. As of that date, PURDUE had neither evaluated nor prepared for submission to the FDA any clinical or epidemiologic study which evaluated or predicted a probable rate of illicit sale or abuse of its ORIGINAL FORMULATION if dispensed by primary care physicians to patients for use on extended or long-term doses on an out-patient basis. Among other things, PURDUE failed to recognize or anticipate the extent to which its 80 mg tablet would become a sought-after opioid by those persons including addicts and their suppliers then engaged in the illicit sales and distribution of narcotics within the US.

D. By 2002, however, PURDUE knew that its ORGINAL FORMULATION was subject to wide-spread illicit diversion and abuse, and that several hundred or more of its prescribing physicians were then acting recklessly and illegally prescribing its ORIGINAL OXYCONTIN product for distribution to addicts or their suppliers. (See 383 LITIGATION, 994 F. Supp.2d at 413 – 414. (Id. Att. 2). Based upon this knowledge, PURDUE had the affirmative obligation[11] to comply with 1997 21 CFR 314.80 and advise the FDA that it had learned from its INTERNAL SALES DATA of a "significant increase in frequency of an adverse drug experience that is both

[11] In his decision, Judge Stein did not also address PURDUE's obligation as "registrant" to comply with the mandatory reporting obligations OF 21 C.F.R. section 1301.71. See n. 4 supra. See Counts SEVEN and EIGHT infra.

serious and unexpected" as defined by that regulation (15-day reporting requirement that applies to any "significant increase in frequency of a serious, expected adverse drug experience" including "overdose [which] is always to be considered serious" (21 CFR 314.80; see n.1. supra).This obligation required among other things PURDUE to advise the FDA of its list of Suspect Physicians and, in addition, of the internal criteria which PURDUE had developed in order to identify the "atypical patterns of prescribing" as an indicator of potential or probable abuse or illegal diversion of the ORIGINAL FORMULATION by such Physicians.

E. Upon information and belief, prior to and during its negotiations with the U.S. Department of Justice, which were concluded prior to the date of its criminal sentencing in 2007, PURDUE did not inform the Department of Justice, the FDA or DEA or any other federal or state law enforcement or public health organization, or Judge Jones (i) of the existence of its INTERNAL SALES DATA that then required PURDUE to make periodic mandatory reports of "significant increases in frequency" of illicit sales and abuse of its product or of the internal conclusions PURDUE had reached based upon its review of that DATA or (ii) of the existence of the "manufacturing problem" it had determined rendered its product unable "to produce its expected pharmacological action". Cf. 1985 21 CFR 314.80 (a) at p 1.

37. As a proximate consequence of PURDUE's (1) aggressive marketing scheme and its knowing and intentional failure to voluntarily restrict sales of its ORIGINAL FORMULATION to only those patients who (i) had a critical need of strong opiate medication and (ii) could be prescribed that medication in a controlled hospital setting where dosages and treatment plans could be carefully monitored until such time when it could develop or acquire licensing rights from third-parties of abuse-proof technologies for its product, and further knowing and

intentional failure to comply with the mandatory reporting obligation imposed on it under 1992 21 CFR section 314.80 ; (2) willful and knowing failure to comply with the mandatory reporting requirements of 21 C.F.R. section 1301.71; and (3) willful and knowing joint enterprise and conspiracy with hundreds or more Suspect Physicians and Suspect Pharmacies to submit or to cause to be submitted false claims to the United States and the State of Vermont in violation of FFCA 3730 (a) (1) (c) and VFCA section 631 (a), PURDUE and each of the DEFENDANT DISTRIBUTORS have forced local, state, and federal governments to expend vast sums of tax payer funds in order to pay for programs that were required to protect the public's health and safety. These programs relate to and involve the immediate "consequences of substance addiction" as well as ongoing "prevention and treatment" programs. Report of New York Attorney General, dated May 2011, "Internet System for Tracking Over-Prescribing (I-STOP)" (Attachment 13). For example, the total expenditures for 2005 have been estimated to have been "at least $467.7 billion – $238.2 billion at the federal level; $135.8 billion at the state level; and $93.8 billion at the local level". (Id. Att. 13 p 10).

A. The total expenditures for 2005 have, for example, been estimated to have been "at least $467.7 billion – $238.2 billion at the federal level; $135.8 billion at the state level; and $93.8 billion at the local level". (Attachment 14: 2009 Report of National Center on Addiction and Substance Abuse, entitled "Shoveling it Up II", Foreword p i).

B. The State of New York spent 21.1% of its General Fund ($13.132 billion) on its "impacted public programs", an amount "which translates to $680.19 per capita". (Id. Att. 14, p 11). By comparison, in 1998 the State of New York spent much less of its General Fund for such programs (about $8.7 billion expended, about 40% less than the amount expended in

2005). (See Table 6.1, submitted as addendum to Att. 14).

C. The per capita expenditure for 2005 for five of the six New England states was as follows: Maine, $893; Vermont, $779; Connecticut, $745; Massachusetts, $699; New Hampshire, $408; and Rhode Island (2005 data not included in report). (Id. Table 4.3 p 40).

D. In 2005 Vermont expended 18.4% of its State Budget on Substance Abuse Programs (Id. Table 4.3). The total amount expended by Vermont for 2005 was $476 Million. By comparison, in 2005 Massachusetts expended 21.8% of its State Budget on Substance Abuse Programs (Id.), an expenditure which totaled for 2005 was $4.5 billion. (Id.).

E. The percentage of State Budget expended for Substance Abuse and Addiction Programs in these five states ranged between Connecticut, at 14.7% and Maine, at 26.9% (Id. Tables 4.3 And 4.4 pp 39 – 40). The total amounts expended in 2005 by these five states for Substance Abuse and Addiction Programs exceeded $8.2 billion dollars. (Id. Table 4.3).

38. From 2001 through the date of its criminal sentencing in 2007, PURDUE failed to develop or acquire licensing rights to use drug-abuse deterrent technology in its ORIGINAL FORMULATION even though such technology was then known and available to other manufacturers of "abuse-proofed controlled release medications" (383 PATENT, paragraph 1, "Background of the Invention" (Id. Att. 6). See also paragraphs 28 – 30 infra. Furthermore, following its federal court conviction, PURDUE failed to limit sales or distribution of its ORIGINAL FORMULATION until it could develop, or acquire, an effective drug abuse-deterrent technology.

39. In 2001 PURDUE undertook through its in-house research and development team to develop "a tablet that would be difficult to crush or to syringe" (383 PATENT LITIGATION, 994

F. Supp 2d at 415) (Id. Att. 2). That effort continued for more than five years but proved unsuccessful. Id. In 2003, as a part of that effort, PURDUE became aware of certain technology which had been developed and patented by Grunenthal GmbH, a German company, of a tamper-proof, crush-resistant tablet. See paragraphs 27 – 29 supra. In "a series of 'long and tough' multi-year negotiations", PURDUE eventually paid Grunenthal more than $220 Million in order to obtain a licensing agreement to use Grunenthal's technology (383 PATENT LITIGATION, 994 F. Supp 2d at 415). (Id. Att. 2). PURDUE began using the Grunenthal technology in its REVISED FORMULATION which it began distributing to pharmacies in 2010. See paragraph 32 – 34 supra.

40. From 2001 through 2010 PURDUE distributed in the United States more than 52 million tablets and realized total product sales in excess of $28 billion of its ORIGINAL FORMULATION. Many of the sales made by PURDUE took place in states where the total sales per capita far exceeded PURDUE's national average sales for the ORIGINAL FORMULATION. For example, PURDUE sold more than 32 million tablets in Florida during the first six months of 2010, a sales volume which "fell by 97%" after Florida enacted "a limit on the number of pills a doctor could dispense". (Id. Att. 3 p 1).

41. Upon information and belief, PURDUE and the DEFENDANT DISTRIBUTORS had obtained and were in possession of sales and distribution records of its ORIGINAL FORMULATION, which PURDUE and its distributors could review on at least a monthly or quarterly basis. This data was contained in such DEFENDANT'S INTERNAL SALES DATA which was obtained (i) by PURDUE sales force and from IMS Health, a third-party information and technology services company then doing business with PURDUE or (ii) by PURDUE and each of

the DEFENDANT DISTRIBUTORS from each pharmacy's "actual dispensing records" that were in the actual or constructive possession of each DEFENDANT[12] and from and other related information from which PURDUE and the other DEFENDANT DISTRIBUTORS could determine by state and county of sale: (i) the names and addresses of each pharmacy which sold its products; (ii) the names and address of each hospital, clinic or physician or other medical provider who prescribed its product to patients; and iii) the actual prescription patterns of prescribing as an indication of potential abuse or illegal diversion of OxyContin as specified in the "SEVEN MANDATORY REPORTING CRITERIA" identified in Paragraph 13 of the 2007 Vermont Consent Judgment. (Attachment 15). See paragraph 51 infra.

A. By 2002 if not before PURDUE had developed certain internal criteria that it used to create a so-called "Region Zero" list, "a confidential roster of physicians [compiled by a panel of three company identified physicians suspected of recklessly prescribing lawyers that] to addicts or dealers" (Attachment 16 (LA TIMES article: "More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew "dated July 10, 2016 by Harriet Ryan, Lisa Girion and Scott Glover, p 5).

B. Purdue did not publically "reveal the existence of [the Zero Region] list ... until 2013". (Id. p 5. By that date Purdue "acknowledged that there were more than 1,800 doctors [that Purdue had identified and placed on its Zero Region list]". (Id.). As of 2013 PURDUE has admitted that it had "reported only about 8% of the doctors on that list to authorities" (id.). In

[12] See id., Masters Pharm., Inc, 861 F. 3d at 222: Distributor is required to request a written document, known as a "UR", to "document customers' explanations for suspicious orders, so that he or she can verify those explanations and make sure they are consistent over time" (citation omitted).

addition, as of that date PURDUE has admitted that it had received from its sales force and others "3,200 reports of suspicious doctors and other prescribers" (Attachment 17 (LA TIMES ARTICLE: "OxyContin maker closely guards its list of suspect doctors", dated August 11, 2013 by Scott Glover and Lisa Girion). In that article a PURDUE representative stated that the company did not have "the ability to take the prescription pad out of their hand" and declined to "say precisely how the company decides which cases to refer to authorities". (id).

C. Upon information and belief, since August 11, 2013 PURDUE has not provided to any federal or state law enforcement or other governmental agency the names and addresses of each doctor it had earlier placed upon its "suspect doctors" list. Furthermore, it has not provided to any law enforcement or other governmental agency the selection criteria it used to determine which of its doctors should be placed on that list. In addition, PURDUE has failed to comply with the provisions of each of the various 2007 Consent Judgments or Settlement Agreements it reached with states such as Vermont, Massachusetts and Rhode Island. See paragraphs 50 - 51 infra.

D. Upon information and belief, the INTERNAL SALES DATA obtained by PURDUE and its DEFENDANT DISTRIBUTORS during the years 2001 – 2010 contains data which, among other things, will be sufficient to identify each physician or physician group who were then engaged in the type of illicit "pill mill" operations that had resulted in the widespread "fraud and abuse activities" identified in the September 2009 report prepared by the United States General Accounting Office "MEDICAID Fraud and Abuse related to Controlled Substances Identified in Selected States" (Attachment 18). The data contained in each DEFENDANT'S INTERNAL SALES DATA should, for the years 2001 – 2010, should be capable of statistical analysis that will

establish by competent evidence each ORIGINAL OXYCONTIN prescription sold or distributed by PURDUE under circumstances that would lead any reasonable pharmaceutical manufacturer or distributor to conclude that the drug was being dispensed for illicit non-medical use and diversion (see, for example, SEVEN MANDATORY REPORTING CRITERIA identified in Paragraph 13 of the 2007 Vermont Consent Judgment (id. Att. 15, quoted in pertinent part in paragraph 51 infra). Furthermore, each DEFENDANT'S INTERNAL SALES DATA should be sufficient to identify each physician or physician group which dispensed ORIGINAL OXYCONTIN for illicit non-medical use and diversion to persons then residing within each state and county where that product was distributed within the United States.

E. At all times material from 2001 to 2010, the Defendant Distributors had "actual knowledge of the information" contained in its INTERNAL SALES AND DISTRIBUTION DATA within the meaning of FFCA section 3729 (b) (1) and was therefore compelled to comply with the mandatory reporting obligations set forth in 1971 21 C.F.R. section 1301.71 (a) and 1983 21 CFR 314.80.

F. This reporting obligation was separate and apart from PURDUE'S mandatory reporting and certification obligations set forth in Section V.C. subparts 1 and 2 of the 2007 Corporate Integrity Agreement. (Attachment 19 at pp 19 – 20 and 29 – 30). PURDUE's failure to report to the FDA the conclusions its employees had reached (particularly its lawyers who then served on PURDUE's "OFFICE OF GENERAL COUNSEL"; see Att. 15 Paragraph 13 of 2007 Vermont Consent Judgement, paragraphs 50 - 51 infra) constitutes one or more purposeful acts, done "knowingly", to intentionally avoid and evade its obligation to disclose such DATA and, in addition, its obligation to report to the FDA PURDUE's conclusions as to

"frequency" in violation of the mandatory reporting obligations established by 1992 21 CFR 314.80. This DATA included but was not limited to reports it had received from its sales force, data supplied to it from IMS Health, and other communications from its" Health Care Providers" (id., Att. 15, Paragraph 13 of 2007 Vermont Consent Judgment) pertinent to illicit distribution of its ORIGINAL FORMULATION and frequency of addiction and over-dose related to such illicit distribution. Furthermore, PURDUE's failure to report such DATA to the FDA constituted (i) ongoing "acts in deliberate ignorance of the truth or falsity of the information [and] acts in reckless disregard of the truth or falsity of [such] information" contained with such DATA in violation of FFCA section 3729 (b) (A) (ii) – (iii) and (ii) a willful and intentional violation of PURDUE's mandatory reporting and certification obligations that PURDUE was required to meet pursuant to the provisions of the 2007 Corporate Integrity Agreement with OIG. See paragraphs 52 - 53 infra.

42. Since 2010 PURDUE has continued to market its REVISED FORMULATION. It sales were about $2.8 Billion in 2011, $2.7 billion in 2012; and 2.46 billion in 2013. Upon information and belief, its total sales, per year, of its REVISED FORMULATION have averaged less than 80% of the sales volume it realized prior to 2010.

43. By July 2012 PURDUE had determined, based upon several post-marketing epidemiological studies, that its REVISED FORMULATION had resulted in noted reductions in OxyContin's diversion, abuse, and street price and recognized a trend involving abusers' substitution of other opiates in the place of OxyContin. See e.g., Attachment 20 (JAMA Intern Med 2015: 175 (6); 978 – 987: "Rates of Opioid Dispensing and Overdose After Introduction of Abuse-Deterrent Extended-Release Oxycodone and Withdrawal of Propoxyphene"). The

conclusions reached by this study were confirmed by the significant overall drop in product sales of PURDUE's REVISED FORMULATION as persons addicted to opiates switched from the ORIGINAL FORMULATION to heroin or other street drugs. See also Attachment 21 (NAEC WORKING PAPER No. 23031 dated January 2017: "Supply-Side Drug Policy in the Presence of Substitutes: Evidence from the Introduction of Abuse-Deterrent Opioids" (OxyContin reformulation significantly reduced non-medical use of OxyContin by as much as 40% (citations omitted), p 324).

44. In March 2013 PURDUE brought a patent infringement action against Teva Pharmaceuticals USA, Inc. (the 383 PATENT LITIGATION, see paragraph 15 supra). On January 14, 2014 the Hon. Judge Sidney H. Stein issued Findings of Fact and Conclusions of Law. PURDUE lost and appealed that that Order which has since been affirmed on appeal. See in re Purdue Pharma, 811 F. 3d 1345 at 1348. (Id. Att. 2).

45. In the patent infringement action, Judge Stein held that PURDUE'S 383 Patent, also known as the "Thermoforming Patent", was invalid because that Patent: (i) was "anticipated and obvious" and (ii) "within the state of the art" when that Patent was issued to Grunenthal in 2012. (994 F. Supp. 2d at 421 –424) (Id. Att. 2) (use of high molecular weight polyethylene oxide to strengthen tablets and make them resistant to crushing was known as early as 1967) (id. p 426); further, use of hot-melt extrusion as a method to promote strengthening of tablet was within the state of art as early as 1999 when Feng Zhang, then a Ph.D. student at the University of Texas, concluded: "[s]ince the polymeric carrier in its melt state during hot-melt extrusion is pressurized inside the extruder, the hot-melt extrudate is anticipated to possess a higher physical strength and lower porosity than tablets prepared by wet granulation and direct

compression methods"(id. p 426).

46. On December 3, 2002 the U.S. Patent Office issued Patent no. 6,488,963 entitled 'HOT-MELT EXTRUDABLE PHARMACEUTICAL FORMULATION" (the "963 Patent") to the University of Texas. (Id. Att. 8). The inventors identified on the 963 Patent were James W. McGinity and Feng Zhang. On or before 2011 the Texas Board of Regents granted an exclusive license under the 963 Patent to Abbott Laboratories whereupon Abbott Laboratories granted an exclusive sublicense to PURDUE. Upon information and belief, PURDUE later modified its manufacturing procedures to include the HOT-MELT FORMULATION of the 963 Patent, which it has employed since that date in the manufacture of its REVISED FORMULATION.

SUMMARY OF 2007 FEDERAL CONVICTION FOR MISBRANDING AND RELATED STATE COURT PROCEEDINGS

47. On July 23, 2007 the sales. Judge James P. Jones agreed to accept a plea agreement entered into between PURDUE and three of its corporate officers and the United States Department of Justice whereby PURDUE pled guilty to "misbranding OXYCONTIN, a prescription opioid pain medication, with the intent to defraud or mislead, a felony under the federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. Sections 331(a), 333 (a) (2)". Cf. United States v. Purdue Pharma Co., 495 F. Supp. 2d at 570 – 571. (Att. 12). That plea agreement was based upon a certain statement of facts which PURDUE (but not its corporate officers) agreed were true for the purposes of the agreement:

... "that beginning on or about December 12, 1995 and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees,

with the intent to defraud or mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications (emphasis added) as follows:

a. Trained PURDUE sales representatives ... told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;

b. Told PURDUE sales representatives they could tell health care providers that OxyContin potentially creates less chance for addiction than immediate-release opioids;

c. Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

e. Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, was less

likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers."

Id. 495 F. Supp. 2d at 570 – 571 (Att. 12).

48. As a part of the plea agreement, PURDUE and its corporate officers paid a total of about $634 Million in fines including (i) payment of about $100 Million to federal government health care agents under a separate Civil Settlement Agreement dated May 8, 2007 (Attachment 22, the "2007 FEDERAL SETTLEMENT AGREEMENT") and (ii) a further payment of about $60 Million to various states which elected "to settle their claims" against PURDUE under that AGREEMENT. However, neither the plea agreement accepted by Judge Jones nor the separate Settlement Agreements reached by more than 49 states (see Attachment 23, United States v. Purdue Frederick Co., 963 F. Supp. 2d 561, 565 (U.S. D.C.W.D.Va. 2013) (I) precluded any claim of "restitution other than as set forth in the agreements" or (ii) "capped" any private claim. Id. 495 F. Supp. 2d at 575 – 576.

49. Among other things, the 2007 FEDERAL SETTLEMENT AGREEMENT was (i) "intended to be for the benefit of the Parties only [and was not intended to] release any claims against any other person or entity [apart from certain claims PURDUE waived for payment of certain "health care billings"] (paragraph 14 – 15) (Id. Att. 22); (ii) applied only to certain "Covered Claims" against PURDUE involving "conduct with respect to the marketing of OxyContin ...during the time period from 1995 through 2005" (emphasis added) (id. paragraphs C and D of Preamble); (iii) and "expressly excluded (emphasis added) from the scope and terms of this Agreement as to any entity or person ... [including] the following:

d. Any liability to the United States (or its agencies) for conduct other

than the Covered Conduct;

f. Any liability for express or implied claims or other claims for defective or deficient products or services, including the quality of goods or services; [and]

g. Any liability or claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct [.]

50. On May 17, 2007 the State of Vermont and PURDUE entered into a certain settlement agreement (the "2007 Vermont Consent Judgment", id., Att. 15). That Judgment was negotiated and entered into by the parties soon after PURDUE entered a plea of guilty to information filed in United States of America v. The Purdue Frederick Company, Inc, et. al. (see id. Att. 12 supra). That Judgment provided in pertinent part the following:

A. that "[] this judgment shall be governed by the laws of the State of Vermont" (id. paragraph 26);

B. that in return for payment of certain unspecified consideration, the State of Vermont through its Attorney General "releases and discharges [PURDUE] of and from any and all civil actions, claims, damages, costs, attorney's fees or penalties that the Attorney General could have asserted against [PURDUE] by reason of any conduct that has occurred at any time up to and including the Effective Date of this Judgment related to or based upon the Subject Matter of this Judgment ("Released Claims")". (id. paragraph 34). Such Released Claims, however, were "subject to the limitations and exceptions set forth in paragraph 36" (see paragraph 40.E. infra).

C. The term "Subject Matter of this Judgment" was defined in the CONSENT

JUDGMENT to mean: "the investigation under the State Consumer Protection Laws of Purdue's promotional and marketing practices (See n. 1 of CONSENT JUDGMENT). .

D. The term the "Effective Date" was defined in the CONSENT JUDGMENT to mean: "the date on which [PURDUE] receives a copy of this Judgment, duly executed [by the parties] and filed with the Court."(See id. Att. 1, Definition section, paragraph I.B).

E. Paragraph 36 of the CONSENT JUDGMENT provides in pertinent part the following: that "[t]he Released Claims set forth in Paragraph 35 specifically do not include the following claims (emphasis added):

(a) private rights of action by consumers, provided, however, that this Judgment does not create or give rise to any such private right of action of any kind;

(b) claims related to Best Price, Average Wholesale Price or Wholesale Acquisition Cost reporting practices or Medicaid fraud or Abuse;

(c) claims of antitrust, environmental or tax liability;

(d) claims for property damage;

(e) claims to enforce the terms or conditions of this Judgment; and

(f) any state or federal criminal liability that any person or entity, including Releasees has or may have to the State of Vermont."

51. Upon information and belief, PURDUE paid the State of Vermont a sum less than $500,000 as consideration for signing the CONSENT JUDGMENT. In addition, PURDUE agreed for a term of 10 years to the following provisions of paragraph 13:

A. that " Purdue shall, no later than thirty (30) business days after the Effective Date of this Judgment, establish, implement and follow an OxyContin abuse and diversion program consisting of internal procedures designed to identify potential abuse or diversion of OxyContin in certain settings (the "OxyContin Abuse and Diversion Detection Program")".

B. that "[t]he Program will apply to Purdue employees and contract or third-part sales representatives ... who contact practicing Health Care Professionals in person or telephone for the purpose of promoting OxyContin".

C. that "[the] Program directs those persons to report to the Office of General Counsel situations, including, but not limited to the following examples, to the extent that such information or activities are observed or learned by them:

(a) an apparent pattern of an excessive number of patients for the practice type, such as long lines of patients waiting to be seen, waiting rooms filled to standing-room-capacity, or patient-prescriber interactions that are exceedingly brief or non-existent;

(b) an atypical pattern of prescribing techniques or locations, such as repeated prescribing from an automobile, or repeated prescribing at atypical times, such as after usual office hours when the Health Care Professional is not on call;

(c) information from a highly credible source or several sources (e.g., pharmacists, law enforcement, other health care workers) that a Health Care Professional or their patients are abusing or diverting medications;

(d) sudden, unexplained changes in prescribing or dispensing patterns that are not accounted for by changes in patient numbers or practice type;

(e) a Health Care Professional who has a disproportionate number of patients who pay for office visits and dispensed medication with cash;

(f) multiple allegations that individuals from a particular practice have overdosed; or

(g) unauthorized individuals signing prescriptions of dispensing controlled substances.

D. that "[u]pon identification of potential abuse or diversion involving a Health Care Professional ..., Purdue will conduct an internal inquiry which will include but not be limited to a review of the Health Care Provider's prescribing history ... and shall take such further steps as may be appropriate under the circumstances which may include ceasing to promote Purdue products to the particular Health Care Professional .... or providing notice of such potential abuse or diversion to appropriate medical, regulatory or law enforcement authorities".

52. On May 7, 2007 PURUDE and the Office of Inspector General of the Department of

Health and Human Services ('OIG") entered into a "Corporate Integrity Agreement" which set forth "compliance obligations assumed by Purdue [for a term of five years] unless otherwise specified". (Id., Att. 19, Section II.A p 1).

A. The Agreement required among other things that PURDUE would appoint a " Compliance Officer [who] shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of this CIA and with Federal health care program and FDA requirements".

B. The Agreement required that the "Compliance Officer shall be a member of senior management of Purdue [and] shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Managers of Purdue [and] shall be responsible for monitoring the day-to-day compliance activities engaged in by Purdue as well as for any reporting obligations created under this CIA. (Id., Att. 19 Section III.A.1 p 4).

C. The purpose of the Agreement was "to promote compliance [by PURDUE] with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs as defined by 42 U.S.C. section 1320a – 7b (f) (Id. Section I p 1).

D. The Agreement, entered into as a part of its 2007 Settlement Agreement with the United States (id., Section I p 1), required PURDUE to adopt certain "Written Standards" as a "Code of Conduct" for its employees which required "all employees [to act in] full compliance with all Federal health care and FDA requirements" (id. Section III.B p 5) and further required PURDUE's Compliance Officer to certify in the Company's "Implementation Report and Annual Reports a certification (i) that "to the best of his or her knowledge", PURDUE "is in compliance with all of the requirements of the CIA and (ii) that "he or she has reviewed the Report and has

made reasonable inquiry regarding its contents and believes that the information in the Report is accurate and truthful" (Id. section V subsections C.1 and C.2).

53. Upon information and belief, at all times material since the date of its CONSENT JUDGEMENT with the Vermont Attorney General's Office, PURDUE has knowingly and with the intent to deceive failed to provide to "any appropriate medical, regulatory or law enforcement authorities" ("Appropriate Authorities") relevant portions of its INTERNAL SALES DATA (see paragraph 36 subparts A – E) which would be "capable of statistical analysis [and] establish by competent evidence [that the ORIGINAL OXYCONTIN product, particularly its 80 mg tablet] was being dispensed for illicit non-medical use and diversion [and] that the "frequency" of such illicit diversion and "addiction and over-dose related to such illicit distribution constituted an "adverse drug experience which [was] both 'serious and unexpected" due to PURDUE's earlier claims, as stated in its NDA 20-553 that the "controlled release composition [was] believed to "reduce the abuse liability of the drug". (Id. Att. 4, paragraph 18 of 2007 Agreed Statement of Facts). Further, upon information and belief, at all times material since the effective date of the 2007 Vermont Consent Judgment, PURDUE has willfully and intentionally failed to provide such information from its INTERNAL SALES DATA and other related information to any of the following Appropriate Authorities: any federal agency including but not limited to the CDC, the DEA, the FDA, or the OIG or any Vermont state agency including but not limited to the Department of Health or the Attorney General's Office or any local or regional or law enforcement agency.

REQUESTS FOR RELIEF

COUNT ONE: REQUESTS FOR DECLARATORY JUDGMENT RELIEF:

54. Pursuant to Rule 57, F.R.Civ.P., Relator request a declaratory judgment in his favor:

A. that the 2007 FEDERAL SETTLEMENT AGREEMENT reached between the Department of Justice and PURDUE (see paragraphs 47 - 49 supra) does not limit or preclude any of the claims for recovery sought by PLAINTIFFS in Counts TWO – EIGHT of this complaint;

B. that the 2007 CONSENT JUDGEMENT between the State of Vermont and PURDUE (see paragraphs 50 – 51 supra) does not limit or preclude any of the claims for recovery sought by Plaintiffs in Counts TWO – EIGHT of this complaint;

C. that the ten year statute of limitations provided by section 3731 (b) (2) FFCA shall apply to the pending action, with the result that Relator may sue and recover from PURDUE for violations under section 3731 (c) FFCA and section 632 VFCA that occurred within 10 years of the date of filing of this complaint, which pursuant to such section relates back to the date of filing of Relator's original complaint on May 26, 2016 in the Massachusetts federal court action supra. Cf. United States ex rel. Williams v. City of Brockton, 2016 U.S. Dist. EXIS 178032 [*26 – 27].

D. that the common law claims of liability asserted in Counts Three - Six of the Complaint on behalf of all Plaintiffs will be subject to the statutes of limitations provided by tit. 12 Vt. Stat. Ann, 511 and that the date of accrual of such statute should be six years from discovery of the injury (that is, discovery of the injury, its cause, and the existence of a cause of action (see Gettis v. Green Mountain Development Corporation, 2005 VT 117 and Politi v. Tyler, 170 Vt. 428, 435 – 436 (2000) (section 511 applicable to all economic loss claims

Attachment 24);

E. that the beginning of the running of the statute of limitations did not commence until on or after May 16, 2016 when Relator filed his original action under seal in the federal court action now pending against PURDUE in the District of Massachusetts (United States ex. rel. Manchester v. Purdue Pharma, L.P. et. al., docket no. 1:16 – cv – 10947 MLW.

F. that the date of accrual of the six year provision has been extended on grounds of fraud pursuant to 12 V.S.A. section 555 for reasons stated in COUNTSTWO – EIGHT infra by an additional period of up to eight years, to a date certain to be determined by the court following production of the discovery sought by PLAINTIFF. See. Attachment 32 (requests to produce Relator seeks to obtain from PURDUE.

G. that Vermont will apply its own statutes of limitations to this action, which will apply to all state law claims asserted by the federal government and by the State of Vermont and by the Vermont Local Government Plaintiffs.

H. that the date of accrual for breach of contract, for common law fraud and statutory consumer fraud are subject to the tolling provisions set forth in tit. 12 Vt. Stat. Ann. 555 (period prior to the discovery of cause of action shall be suspended for fraudulent concealment prior to the date of discovery of cause of action). See Count SEVEN, paragraphs 96 – 102 ; and Count EIGHT, paragraphs 103 – 107 infra).

I. that the common law claims of liability asserted in Counts Three – Eight of the Complaint will be subject to the statutes of limitations set forth in Chapter 23, 12 Vt.Stat. Ann. sections 511 et seq. under applicable choice of law rules of the forum state. .

COUNT TWO: REQUESTS FOR DAMAGES UNDER THE FEDERAL AND STATE OF VERMONT FALSE CLAIMS ACT:

55. RELATOR adopts PARAGRAPHS 1 – 54 as a part of COUNT TWO.

56. During 2006 – 2016 and at all other times material to this complaint, the UNITED STATES and the State of Vermont have processed and made payment to health care providers for numerous prescriptions for the ORIGINAL FORMULATION of OxyContin. As a part of its cooperative venture with the participating states and territories, the federal government, has made payment to such states and territories in an "amount equal to [its share of] the federal medical assistance program percentage [Medicaid Reimbursement Percentage]" (963 F. Supp. 2d at 564) (Id., Att. 25).

57. Upon information and belief, the Medicaid Reimbursement Percentage in effect for the State of Vermont during the years 2002 – 2016 was more than 50% with the result that the federal government reimbursed the State of Vermont for more than 50% of all OXYCONTIN CLAIMS (including office visits and related health-care services and prescription costs to purchase OxyContin) paid by the State of Vermont during those years. During such years the Medicaid Reimbursement Percentage in effect for all participating states and territories varied between a low of 50% and a high of 82% ("PARTICIPATING STATES or TERRITORIES").

58. Upon information and belief, one or more of the following FEDERAL GOVERNMENT PAYORS made payment for OXYCONTIN CLAIMS submitted to it by PARTICIPATING STATES or TERRITORIES under the Medicaid Program, established pursuant to Title XIX of the Social Security Act, 42 U.S.C. sections 1396 – 1396v; the TRICARE Program (f/k/a the Civilian Health

and Medical Program of the Uniformed Services ("CHAMPUS"), 10 U.S.C. sections 1071 – 1110; the Federal Employees Health Benefits Program ("FEHBP"), which is administered under programs under the Federal Employees' Compensation Act" ("FECA"); 5 U.S.C. section 810 et seq, the Energy Employees Occupational Illness and Compensation Act ("EEOICPA"), 42 U.S.C. section 7384 et seq; and the Black Lungs Benefits Act ("BLBA"), 30 U.S.C. section 901 et seq, administered by the DOL Office of Workers' Compensation Programs ("OWCP") and/or the Department of Veterans Affairs ("DVA").

59. Upon information and belief, each OXYCONTIN CLAIM paid either by the federal government or by each PARTICIPATING STATE or TERRITORY including but not limited to the State of Vermont was in response to a CLAIM FOR PAYMENT submitted by a health care provider in such state or territory. Further, each such CLAIM FOR PAYMENT required a certification that each OXYCONTIN CLAIM involved a medical visit or service provided by a health care professional which was medically necessary for treatment of the health care needs of the patient. See, e.g., Definition of Medical Necessity, Vermont Medicaid Rule 7103 (Attachment 25).

60. Upon information and belief, PURDUE and its DEFENDANT DISTRIBUTORS had actual knowledge through their INTERNAL SALES DATA and other related information (maintained to provide PURDUE with sales information involving physician profiles and their prescribing practices) that a significant number of their physician-customers were engaged in an illegal enterprise whereby they wrote prescription slips and/or purchased for illicit distribution vast quantities of the ORIGINAL FORMULATION for diversion to persons then addicted to OxyContin or to their suppliers. See paragraph 36.A – 36.F supra.

61. Upon information and belief, on or before 2002 PURDUE "had identified hundreds of doctors who were prescribing OxyContin recklessly" (Attachment 26, Pacific Standard article dated March 4, 2015 by Mike Mariani, "How the American opiate epidemic was started by one pharmaceutical company" p 5 – 6). Further, during such time, PURDUE as "applicant" under 21 C.F.R. section 314.80 and as "registrant" and "distributor" under 21 C.F.R. section 1307.71 (a) had the mandatory obligation to disclose to the FDA and the DEA its knowledge of such illicit practices and the names of the physicians and pharmacies it knew were then engaged in such practices. See n. 1 – 8 supra.

62. Upon information and belief, PURDUE did not disclose the information they had obtained from their INTERNAL SALES DATA and other related information to either the FDA or to the United States Drug Enforcement Administration ("DEA") or the DEA Office of Diversion Control prior to July 23, 2007 when Judge Jones accepted the plea bargain agreement between PURDUE and the Department of Justice (see paragraphs 47 – 49 supra) or at any time thereafter through the date of the original complaint).

63. Instead, PURDUE undertook, during the years 2002 – 2010, to actively promote and sell and distribute its ORIGINAL FORMULATION to providers whom it had identified as physicians who were "recklessly" prescribing OxyContin to Medicaid patients under circumstances which indicated that most, if not all, of the distributions and sales to this group were being written for purposes of illicit product diversion of a Class II controlled substance, a known violation of Vermont Medicaid Regulation 7103 supra (Id. Att. 25). See paragraphs 36.A – 36.E supra. PURDUE therefore had actual knowledge that physicians identified on its INTERNAL SALES DATA had engaged, and continued to engage, in the preparation and

submission of false claims for payment in violation of Vermont Regulation 7103 supra, and related federal and state regulations. See paragraph 10 supra.

64. Further, PURDUE had actual knowledge that its "reckless" physician group was over-prescribing the ORIGINAL FORMULATION of OxyContin to patients who were then engaged in a variety of "pill mill" illegal enterprises (see, e.g., illicit schemes to defraud Medicaid identified in U.S. v. Jackie Mize et al, 2012 WL 75440 (6th Cir. 2016). (Attachment 27) and knew or had the opportunity to know that the DEFENDANT DISTRIBUTORS had either failed to report to the DEA "suspicious orders" (see n. 3 supra) or had willfully falsified the pharmacy orders filled by such DISTRIBUTORS in violation of the mandatory reporting obligations of 21 C.F.R. section 1301.77.

65. PURDUE's knowledge of such activities by its "reckless" physician group, coupled with PURDUE's continuing efforts to distribute additional supplies of its ORIGINAL FORMULATION to such groups, constitutes ample proof that at all times material during the years 2002 – 2010, PURDUE engaged in the commission of a conspiracy in violation of 18 U.S.C.A. section 371 and FFCA section 3729 (a) (1) (c). This conspiracy involved among other things the operation of an illegal enterprise whereby PURDUE and the DEFENDANT DISTRIBUTORS knowingly placed into the stream of commerce vast quantities of the ORIGINAL FORMULATION for illicit consumption by thousands of Americans then addicted to that product in violation of 21 U.S.C. section 823 (b) and (e). This conspiracy continued even after the FDA requested PURDUE to remove its product PALLADONE from the market due to "drug-dosing" concerns in 2005. See Attachment 28: Statement of Robert J. Meyer, Director of Office of Drug Evaluation II, re "FDA's Role in Preventing Prescription Drug Abuse", presented to U.S.

House of Representative's Committee on Governmental Reform on September 13, 2005 at pp 285 – 285 (Palladone suspension ordered by FDA after initial approval based upon "new evidence ... that current formulation [of this Class II opioid] presented an unacceptable level of risk").

66. Relator asserts that each sale or distribution of its ORIGINAL FORMULATION to providers PURDUE had identified as "reckless" on its INTERNAL SALES DATA constitutes a purposeful act that resulted in and "caused to be made" the submission of numerous false claims for payment to the UNITED STATES and all PARTICIPATING STATES or TERRITORIES including but not limited to the State of Vermont in violation of section 3729 (a), subparts (a)(B) and (a) (C) FFCA and section 5B (a) MFCA. Relator therefore seeks as damages on behalf of the UNITED STATES and the STATE OF VERMONT the following:

A. Payment of a civil penalty in the amount allowed pursuant to sections 3729(a) FFCA and 5B (a) MFCA and/or three times the amount of actual damages sustained by the UNITED STATES and the STATE OF VERMONT for each act constituting a violation of such sections and

B. All reasonable costs of attorneys' fees, expert fees and all costs of investigation, penalty or damages", as allowed pursuant to section 3730 (d) FFCA and/or section 631(b) VFCA.

COUNT THREE: REQUESTS FOR DAMAGES ARISING UNDER RESTATEMENT (SECOND) OF TORTS section 402A (1965):

67. RELATOR adopts adopt PARAGRAPHS 1 – 66 as a part of COUNT THREE.

68. PURDUE and each DEFENDANT DISTRIBUTOR, as manufacturer and/ or distributor

of the ORIGINAL FORMULATION, is strictly liable to PLAINTIFFS for the property damages each incurred as asserted supra in paragraphs 37.A – 37.E. These damages include its TOTAL SPENDING for SUBSTANCE ABUSE and ADDICTION for the years 2002 – 2010 for addiction caused by or related to the ORIGINAL FORMULATION, as apportioned by the ratio of GROSS SALES PER YEAR OF THE ORIGINAL FORMULATION divided by the GROSS SALES PER YEAR OF ALL OTHER OPIATE CLASS II PHARMACEUTICAL PRODUCTS SOLD TO US or VERMONT RESIDENTS DURING SUCH YEARS.

69. During 2002 – 2010 and at all times material to this complaint, PURDUE and the DEFENDANT DISTRIBUTORS sold and/or distributed a class II opioid product, its ORIGINAL FORMULATION, to thousands of persons then in all US states and territories including the State of Vermont while such product was in an unreasonably dangerous and defective condition. When sold, each unit of the ORIGINAL FORMULATION was defective because when sold or distributed to residents of all US states and territories, the pill matrix of the ORIGINAL FORMULATION lacked sufficient physical or chemical hardness to prevent inadvertent or deliberate tampering of the tablet with the result that the product was unsafe for its intended use to treat patients with complaints of "moderate to severe pain" over a course of treatment "for more than a few days" (NDA 20-553, id. Att. 1; see paragraphs 15 – 16, and 20 – 24 supra) because:

A. the dosage of oxycodone (the active opioid ingredient of the ORIGINAL FORMULATION) was "approximately twice as potent as oral morphine on a milligram basis" (paragraph 22 supra);

B. The ORIGINAL FORMULATION "combined several doses worth of oxycodone – a

powerful opioid -- into a single tablet [which was intended to release] the oxycodone over a twelve-hour extended release profile" (383 PATENT LITIGATION, 994 F. Supp. 2d at 414). (Att. 2). This release mechanism, however, "was susceptible to tampering, since abusers could crush the tablets easily into powder, which resulted in the time release aspect of the formulation being destroyed and the opiate being released at once" (Id.).

C. In its NDA-20553 PURDUE claimed that "the safety and effectiveness of its ORIGINAL FORMULATION was dependent upon the time-release mechanism of its product, which PURDUE stated was "believed to reduce the abuse liability of [its product]". When it made that claim, PURDUE knew that the "wet granulation and direct compression methods" it had employed to construct its pill matrix (see paragraph 45 supra) rendered the product susceptible to tampering by persons addicted to opiates.

D. In 1995 when it filed NDA-20553 PURDUE knew or had reason to know that "abusers could crush the [ORIGINAL FORMULATION] tablets easily into powder [with the result that] the opiate [would be] released at once" (383 LITIGATION, 994 F. Supp. at 414 (Id. Att. 2). See paragraph 26 supra). See 2007 AGREED STATEMENT OF FACTS, wherein PURDUE admitted that its "...own study showed that a drug abuser could extract approximately 68% of oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe" (Att. 4 p 6);

E. In February 1999 PURDUE became aware that more than a dozen patients in clinical studies it had funded had developed symptoms "possibly related to opioid withdrawal" while using the ORIGINAL FORMULATION (2007 AGREED STATEMENT OF FACTS, paragraphs 30 – 35 (Att. 4 pp 10 – 12);

F. Prior to February 1999 PURDUE "investigated ways to reformulate OxyContin to deter abuse". This in-house effort occurred after PURDUE "had begun to develop abuse-deterrent technologies in the 1990's" when PURDUE had "focused on addressing other frequently abused drugs besides OxyContin [and] other methods of abuse besides snorting and injecting" (383 PATENT LITIGATION, 994 F. Supp. 2d at 415) (Id. Att. 2).

G. In 2001 PURDUE's "research and development team" made the decision to develop "a tablet that would be difficult to crush or to syringe" (383 PATENT LITIGATION, 994 F. Supp. 2d at 415; see paragraph 39 supra). As of this date PURDUE then knew that its ORIGINAL FORMULATION did not contain a suitable "controlled release mechanism" which was intended to prevent "parenteral, nasal and/or oral abuse of [the] pharmaceutical active ingredients [of its product and its] abuse potential". 383 Patent, p 2, claim No. 30 (Att. 6; paragraph 26 supra);

H. In 2004 or before PURDUE became aware of certain technology that "had been developed and patented by Grunenthal GmbH, a German company, of a tamper-proof, crush-resistant tablet" (see id. 994 F. Supp. 2d at 415 and paragraph 39 supra). In this effort, PURDUE knew or had reason to know that other pharmaceutical companies or university-funded researchers in the field of pill matrix design and construction had begun to use "high molecular weight polyethylene oxide to strengthen tablets and make them resistant to crushing" (paragraph 45 supra) and that several of these researchers claimed that their "hot-melt extrusion" process was capable of producing "higher physical strength and lower porosity tablets [than those] tablets prepared by wet granulation and direct compression methods" (1999 Zhang publication, see paragraph 45 supra).

I. In 2007 PURDUE submitted NDA-022272 to the FDA. By this date PURDUE had acquired from Grunenthal GmbH a license to use its "abuse-proof formula" (paragraph 27 supra). The FDA approved that NDA in 2010, provided that PURDUE "conduct epidemiological studies to address whether the changes [the REVISED FORMULATION] actually resulted in a decrease in the risks of misuse and abuse, and their consequences" (Id).

J. By acquiring licensing rights to Gruenthal's "ABUSE-PROOFED DOSAGE" patent (the 383 PATENT; see paragraph 27 – 29 supra), PURDUE acquired for the first time the ability to produce an "extremely hard" tablet sufficient in design and construction to prevent crushing or injecting of the product, a necessary first-step toward developing an abuse-proof tablet (Id.). Thereafter, PURDUE obtained a separate license to use the "hot-melt extrusion process" which researchers had first developed in 1995. In their 1999 patent application, these researchers claimed that their process was "particularly well suited for oral delivery ... [of] ...controlled-release pharmaceutical formulations" (paragraph 30 supra).

K. In August 2010 PURDUE discontinued production of its ORIGINAL FORMULATION and limited further production to its REVISED FORMULATION which it began to distribute after the supplies of its ORIGINAL FORMULATION had run out.

L. In July 2012 or before PURDUE had determined, based upon its post-marketing studies, that its REVISED FORMULATION had resulted in noted reductions in diversion, abuse, and street price of its new product, and recognized a trend involving abusers' substitution of other opiates including heroin as a substitute for its ORIGINAL FORMULATION.

70. At all times material between 1995 and 2010, PURDUE had actual knowledge that its ORIGINAL FORMULATION lacked the necessary hardness to prevent or substantially reduce

the risk that persons addicted to opiates would use it to further their addiction. See paragraph 20 - 25. PURDUE therefore had the duty to foresee that a vast number of users of its product would crush the tablet and use it as a ready and easily available source of opiates to further their addiction. Furthermore, the INTERNAL SALES DATA and other related information which PURDUE and its distributors received after 2001 demonstrated that numerous physicians and/or physician groups were then engaged in illicit "pill mill" operations that involved widespread "fraud and abuse activities", as identified in the September 2009 GAO report (id. Att. 18).

71. At all times material between 1995 and 2010, the ORIGINAL FORMULATION was defectively designed and unsafe for its intended use because it lacked the hardness needed to avoid widespread use by addicts as a ready source of opiates to further their addiction:

A. In 1995 when it submitted NDA-20553 to the FDA, PURDUE then knew or should have known that its ORIGINAL FORMULATION lacked the hardness required to prevent addicts from crushing the product in order to obtain a ready source of opiates to further their addiction (see paragraph 69, subparts [A] – [D]);

B. In 1999 PURDUE received reports that patients in its clinical trials had developed symptoms of opiate addiction while under the care of physicians then supervising PURDUE'S trials (see paragraph 69, subpart [E];

C. By 2001 PURDUE through its research and development team knew that the ORIGINAL FORMULATION was defective because it lacked a suitable "controlled release mechanism" and further knew that this defect had resulted in wide-spread reports of addiction caused by addicts who crushed that product for purposes of obtaining ready sources of opiates

to further their addiction (see paragraph 69 [F]);

D. In 2001 if not before, PURDUE had actual knowledge through its SALES AND DISTRIBUTION DATA and other related information that numerous physicians and/or physician groups were then engaged in illicit 'pill mill" operations, and continuing to purchase or write scripts to their patients of the ORIGINAL FORMULATION for off-label uses of that product (see paragraph 41.A – 41.F supra);

72. PURDUE'S negligent failure to research and design a revised pill matrix prior to 2004 when it obtained a license to use Grunenthal's "ABUSE-PROOFED DOSAGE FORM" (see paragraphs 27 - 28 supra) and further failure to restrict its marketing and distributing of its ORIGINAL FORMULATION until such time that it could design or acquire the licensing rights to use the Grunenthal 383 PATENT was a proximate cause of the public health epidemic which began shortly after marketing of the product in 1996 and exponentially worsened prior to 2001 when PURDUE first took steps to design and construct "an abuse-proof tablet" (see paragraph 29 supra).

A. During such time, the epidemic worsened as PURDUE's annual product sales grew to more than $3.0 billion per year (see paragraph 19 supra).

B. During such time, PURDUE failed to follow then-recognized and accepted state of the art practices known to and employed by competitors within the pharmaceutical industry related to the design and construction of a pill matrix intended to be used as a controlled release platform of an opiate medication then classified as a Class II pharmaceutical product.

C. Such failure was negligent as contrary to the standards of reasonable care then practiced within the domestic and international pharmaceutical industry. This failure

constituted a proximate cause of the public health epidemic created by sales of the ORIGINAL FORMULATION to pharmacies located throughout the United States. This failure required federal, state and local governments to expend vast sums of tax payer funds which were and have been required to protect their public's health and safety. See paragraph 37 supra.

73. In addition, PURDUE and each DEFENDANT DISTRIBUTOR should be held strictly liable without regard to proof of fault for its defective design and construction of the ORIGINAL FORMULATION:

A. In its NDA 20-553 PURDUE claimed that its ORIGINAL FORMULATION would "provide increased convenience in dosing appropriate patients" and stated in its proposed labeling that its product would provide "for the management of moderate to severe pain in patients where use of an opioid analgesic is indicated for more than a few days". The FDA approved this NDA on December 12, 1995 (see Att. 1 p 1) by stating we "have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed draft labeling".

B. On September 18, 1996 the FDA approved NDA 20-553/S-056 which PURDUE had submitted in connection with its request to market an 80 mg tablet. In its submission, PURDUE claimed that its clinical studies indicated that "there appears to be no obvious clinical problems with the new dosage strength [80mg]". (Att. 1 p. 1).

C. In NDA 20-553 PURDUE identified its 042 PATENT (Att. 5, see paragraph 26 supra). In that PATENT PURDUE identified several types of coatings it intended to use in order to create a "controlled release mechanism" but failed to identify any physical or chemical means which it

expected would prevent "parenteral, nasal and/ or oral abuse of [the] pharmaceutical active ingredients [of its product and its] abuse potential" (see paragraph 16, claim set forth in 383 PATENT (Att. 6 supra).

D. In NDA 20-553 PURDUE claimed that its researchers stated their belief that the product's time-release mechanism would "reduce the abuse liability" of the product even though they then knew that their product (i) was "approximately twice as potent as oral morphine on a milligram basis" (paragraph 22 supra); (ii) then contained "several doses worth of oxycodone – a powerful opioid – into a single tablet" (paragraph 36 supra); and (iii) and would allow a drug abuser to "extract approximately 68% of oxycodone from a single 10mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe" (paragraph 47.a supra).

E. In 1999 PURDUE learned that more than a dozen patients in one of its clinical studies had developed symptoms "possibly related to opioid withdrawal" (paragraph 69 [E] supra). That same year PURDUE took steps to investigate "ways to reformulate OxyContin to deter abuse" (paragraph 69 subpart G supra).

F. In 2001 PURDUE made the decision to develop "a tablet that would be difficult to crush or to syringe" (paragraph 69 subpart G supra).

G. In 2004 PURDUE became aware of the Grunenthal GmbH process for producing a "tamper-proof, crush resistant tablet" and took steps thereafter to acquire licensing rights to Gruenthal's 383 PATENT (paragraph 69 subpart H supra).

H. In 2010 the FDA approved NDA 022272. PURDUE had filed this NDA in 2007. This filing pertained to "an abuse-proof formulation", the REVISED FORMULATION. In 2013 PURDUE

obtained from the FDA approval of new Labelling which allowed it to claim that its new product contained an abuse-proof formula "for treatment of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time" (Att. 10 p 1).

74. For reasons set forth in paragraph 69 PURDUE and each DEFENDANT DISTRIBUTOR should be held strictly liable without regard to proof of fault for the various design defects it failed to correct prior to distributing the ORGINAL FORMULATION in 1996 and through 2010 when such DEFENDANTS began to distribute its REPLACEMENT FORMULATION:

A. In 1996 PURDUE had actual knowledge that the pill matrix of its ORIGINAL FORMULATION lacked the physical or chemical hardness necessary to prevent product misuse by persons intending to crush the tablet in order to overcome the product's time-release mechanism and release "at once" the full strength of the narcotic then present within the tablet (see paragraphs 21 – 22 supra);

B. In 1996 PURDUE had conducted certain in-house research which had "focused upon other frequently abused drugs ... and other methods of abuse besides snorting and injecting" (paragraph 69 subpart F). From this research PURDUE knew or should have known that its claim, as stated in NDA 2- 553, that its "twelve-hour release profile" would "reduce the abuse liability of [its product] was unfounded and contrary to the in-house crushing tests it had earlier conducted (see paragraph 69 subpart C supra);

C. In 2001 PURDUE made the decision to develop "a tablet which would be difficult to crush or to syringe" (paragraph 69 subpart G). As of this date PURDUE knew or should have known (i) that other pharmaceutical manufacturers of time-release products including but not

limited to products containing opioid analgesic medications had begun to "use high molecular weight polyethylene oxide to make [their products] resistant to crushing" (paragraph 45 supra) and (ii) that the "hot-melt extrudate" process developed by University of Texas researchers in 1999 rendered obsolete prior methods of producing opiate time-release by "wet granulation and direct compression methods" (paragraph 45 supra).

D. By 2002 PURDUE had actual knowledge through its INTERNAL SALES DATA and related information (see paragraphs 41.A – 41.F supra) that a substantial quantity of its ORIGINAL FORMULATION product had been "recklessly" prescribed by hundreds of its physician-customers who were engaged in an illegal enterprise whereby they wrote prescription slips and/or purchased for illicit sale vast quantities of the ORIGINAL FORMULATION for diversion to persons then addicted to OxyContin or their suppliers.

E. In 2004 PURDUE became aware of the Grunenthal patent application and manufacturing technology involving the '383 PATENT for an "abuse-proof formulation" (paragraph 27 supra). PURDUE obtained licensing rights for this technology and three years later filed NDA 022272 (id.). In 2010 the FDA granted approval of PURDUE's NDA and allowed PURDUE to market its REVISED FORMULATION but required it to conduct certain epidemiologic to evaluate whether the REVISED FORMULATION would demonstrate suitable "abuse-deterrent properties". In 2013 the FDA authorized PURDUE to revise its labeling for the new product and market its product as having such properties. See paragraph 31 supra.

F. By 2011 PURDUE acquired a license to use the 963 PATENT earlier patented by University of Texas researchers in 2002. That PATENT pertained to the "hot-melt extrusion process" which the researchers had first published in 1997 and described as "particularly well

suited for oral delivery ... [of]... controlled release pharmaceutical formulations" (paragraph 30 supra).

G. In 2001 if not before, PURDUE knew or should have known of the existence of the 963 PATENT and should have then pursued a licensing agreement in order to obtain the right to use that process in the manufacture of its REVISED FORMULATION.

75. Relator asserts that it was economically and scientifically feasible for PURDUE to have developed or acquired the technology it used to develop its REVISED FORMULATION prior to 2002, the date when PURDUE had actual knowledge that its "ORIGINAL FORMULATION was subject to wide-spread abuse and that several hundred or more of its prescribing physicians were then acting recklessly and illegally prescribing its ORIGINAL FORMULATION product for distribution to addicts or their suppliers" (Paragraph 38 supra).

76. Relator seeks to recover on behalf of each PLAINTIFF its TOTAL SPENDING for SUBSTANCE ABUSE and ADDICTION which was caused by and related PURDUE'S sales and distribution of ORIGINAL OXYCONTIN during the years 2002 – 2010. As a proximate result thereof, PURDUE and each DEFENDANT DISTRIBUTOR should be liable to each PLAINTIFF for that PLAINTIFF'S actual and punitive damages, as follows:

A. the amount of actual and consequential damages sustained by each such PLAINTIFF for the years 2002 – 2010 as a part of their spending on SUBSTANCE ABUSE and ADDICTION for or on behalf of persons addicted to ORIGINAL OXYCONTIN, which expenditures are separate and apart from the health care services and products it paid for as a part of its MEDICAID REIMBURSEMENT PROGRAM. This amount, upon information and belief, exceeded the sum of $500 million per year during each year from 2002 to 2010; see Attachment 29: Summary of

Federal Spending on Substance Abuse and Addiction for 2005, Table 3.1 at p 20 of May 2009 Report of National Center on Addiction and Substance Abuse.

B. the amount of actual damages sustained by the UNITED STATES, the STATE OF VERMONT, and each VERMONT LOCAL GOVERNMENT PLAINTIFF for the years 2002- 2010 Medicaid for false claims submitted for payment by PURDUE's Suspect Physicians in violation of MEDICAID MEDICAL NECESSITY STANDARDS (see paragraph 10 supra) and

C. punitive damages equal to three times the actual damages sustained by each such PLAINTIFF during those years.

COUNT FOUR: REQUEST FOR DAMAGES UNDER EQUITABLE DOCTRINE OF UNJUST ENRICHMENT:

77. RELATOR adopts PARAGRAPHS 1 – 76 as a part of COUNT FOUR.

78. PURDUE and each DEFENDANT DISTRIBUTOR has been unjustly enriched by the gross revenues and profits each DEFENDANT has received as a consequence of the sale and distribution for sale of the ORIGINAL FORMULATION to US consumers between 1996 and 2010.

79. Upon information and belief, PURDUE and each DEFENDANT DISTRIBUTOR have sold or distributed for purposes of sales more than 50 million ORIGINAL FORMULATION and have realized gross sales during those years in an amount in excess of $25 billion. During such years PURDUE and the DEFENDANT DISTRIBUTORS have manufactured or distributed for purposes of sale within the United States millions of prescriptions of its ORIGINAL FORMULATION. These prescriptions which amount to more than 45 tons of defective product sold to US consumers, are proximate consequences of the public health epidemic which began in 1996 and grew exponentially before PURDUE replaced that product in 2010 with its REVISED FORMULATION (see Att. xx supra). qq

80. In 2001 PURDUE's "research and development team" made the decision to develop "a tablet that would be difficult to crush or to syringe" (383 PATENT LITIGATION, quoted supra paragraph 39), a decision it made after it became aware through its INTERNAL SALES DATA and other related information that "a significant number of [its] physician-customers were engaged in an illegal enterprise whereby they wrote prescription slips or purchased vast quantities of the ORIGINAL FORMULATION for illicit diversion to persons then addicted to OxyContin or their suppliers" (paragraph 17 supra). Notwithstanding such knowledge, PURDUE undertook during the years 2001 – 2010 "to actively promote and distribute its ORIGINAL FORMULATION to providers it had identified as physicians who were "recklessly" prescribing OxyContin to Medicaid patients under circumstances which indicated that most, if not all, of the distributions and sales to this group were being written for purposes of illicit product diversion of a Class II controlled substance in violation of applicable Medicaid Rules and DEA statutes and regulations (see n.1 – 8 supra). Such efforts after 2001 constitute knowing participation in "a variety of 'pill mill' activities in violation of 18 U.S.C.A. section 371 (id).

81. At all times material between 1995 and 2010, PURDUE knew as a result of its own tests that its ORIGINAL FORMULATION could be easily crushed with the result that the opiate contained in its tablet would be "released at once" (paragraph 69, subparts C - D):

A. By 2004 PURDUE had actual knowledge of the Grunenthal GmbH "abuse-proof formula" (id. subparts I – J);

B. By 2004 PURDUE knew or should have known that its competitors had developed various physical and chemical methods whereby they were able to produce "tamper-proof and crush-resistant" tablets for use in the manufacture of "controlled release" pharmaceutical products (paragraph 69 subparts A - B).

C. By 2004 PURDUE new or should have known that the "hot-melt extrudate" process

would render "obsolete prior methods of producing opiate time-release tablets by 'wet granulation and direct compression methods'" (paragraphs 45 and 69 subpart C.

82. Upon information and belief, PURDUE sold more than $15 billion of its ORIGINAL FORMULATION to US consumers during 2004 – 2010. Further, during such time, PURDUE knew or had reason to know that a substantial quantity of that product had or would be diverted for illicit use. See paragraph 17 supra.

83. PURDUE's failure to manufacture and sell a "tamper-proof and crush resistant tablet" (paragraph 69 subpart H supra) after 2004 and until 2010 when it began to sell and distribute its REVISED FORMULATION constitutes negligence "as contrary to the standards of reasonable care then practiced within the domestic and international pharmaceutical industry" (paragraph 69 subpart C). Further, for reasons stated in paragraph 69 subparts A – G, PURDUE and the DEFENDANT DISTRIBUTORS should be held strictly liable without regard to fault for its knowing and repeated sales of a defectively designed product prior to 2010, the date when it first began to distribute its REVISED FORMULATION and the knowing and willful failure of PURDUE and the DEFENDANT DISTRIBUTORS to comply with the mandatory reporting obligations set forth in 21 C.F.R. section 1301.77 (see n.4 supra).

84. Under principles of equity, PURDUE and each DEFENDANT DISTRIBUTORS should therefore be required to disgorge all profits which it has unjustly realized as a consequence of the sales and/or distribution each realized from the ORIGINAL FORMULATION after June 2004. See Restatement (Third) of Restitution and Unjust Enrichment section 3, comment c (2011) (restitution requires full disgorgement of profit by a conscious wrongdoer). Further, PURDUE should be required to assign to Relator for subsequent assignment by Relator to a federal or private not-for-profit university and/or research facility all of its current patents or licenses to use patents owned by third-parties that relate to its ORIGINAL FORMULATION or

REPLACEMENT FORMULATION for possible construction of a tapered-dosage opioid tablet for use by health care providers in the treatment of persons now addicted to heroin and other forms of opioids.

COUNT FIVE: REQUEST FOR DAMAGES FROM ALL DEFENDANTS AND INJUNCTIVE RELIEF AGAINST PURDUE PURSUANT TO THE VERMONT CONSUMER PROTECTION ACT (tit. 9 Vt. Stat. Ann. section 2451 et seq.)

85. RELATOR adopts PARAGRAPHS 1 – 84 as a part of COUNT FIVE.

86. At all times material between 2002 and 2010 PURDUE and each DEFENDANT DISTRIBUTOR actively solicited and sold and distributed for purposes of sale to physicians and pharmacies then located within the State of Vermont s vast quantities of its ORGINAL FORMULATION product after each DEFENDANT had actual knowledge that a substantial portion of such sales, particularly sales of its 80 mg tablet, were being made to Vermont physicians whom PURDUE had earlier identified and placed on their list of "Suspect Physicians" (see paragraph 34 supra). This data was contained in its INTERNAL SALES DATA and other related information which had been obtained by the PURDUE sales force and from IMS Health, a third-party information and technical services company then doing business with PURDUE. From such DATA and other information. PURDUE and each DEFENDANT DISTRIBUTOR knew and had reason to know of the actual prescription patterns followed by each Suspect Physician or each Suspect Pharmacy (see paragraph 41A – 41.E supra) and therefore knew and had the opportunity to determine from such DATA and other related information which of its Suspect Physician or Suspect Pharmacy Customer was then actively engaged in the illegal prescription and dispensing of ORIGINAL OXYCONTIN for purposes of illicit non-medical use and diversion to persons then addicted to opioids or their suppliers.

87. During such time PURDUE as "registrant" knowingly and with the intent to deceive

failed to disclose to the FDA, the DEA or other federal or state public health or law enforcement agencies located within the State of Vermont or elsewhere that it had actual knowledge that several hundred or more of its Suspect Physicians and Suspect Pharmacy Customers were "recklessly" and illegally prescribing its ORIGINAL FORMULATION product, particularly the 80 mg tablet, for distribution to addicts or their suppliers. PURDUE continued its deception even after the State of Vermont and other states obtained CONSENT JUDGMENTS which required PURDUE to identify and report to governmental officials physicians who PURDUE and its sales force believed were engaged in "atypical patterns of prescribing" as described in the "SEVEN MANDATORY REPORTING CRITERIA" identified in the 2007 Vermont Consent Judgment (see paragraph 41 supra). This failure among other things constitutes a willful and intentional failure on the part of PURDUE to comply with the reporting and certification requirements of the Corporate Integrity Agreement it signed with OIG in 2007 (see paragraphs 41.E and 52 – 53 supra) and the mandatory reporting obligations of 21 C.F.R. section 1301.77 (see n. 6 – 8 supra).

88. During such time PURDUE as "applicant" knowingly and with the intent to deceive failed to comply with the mandatory reporting obligations set forth in 1992 21 CFR 314.80, specifically the frequency" of illicit abuse and distribution and resulting "serious and unexpected" adverse drug experience which increased to epidemic proportions within five years after it received approval by the FDA of NDA 20 – 553 in 1995. See n.1, 3 - 4 supra and see paragraphs 41.A – 41.B.

89. During such time PURDUE knowingly and with the intent to deceive continued to sell and distribute ORIGINAL FORMULATION to its Suspect Physicians and Suspect Pharmacies then located within the State of Vermont and elsewhere even though it then knew or should have known from its INTERNAL SALES DATA and other related information that a majority of

such sales were paid for by Medicaid as a part of an illegal conspiracy by such Physicians or Pharmacies to obtain payment by Medicaid through submission of false claims in violation of the Medicaid Medical Necessity Standards (see paragraph 10 supra).

90. In addition, PURDUE's knowing and active participation in the illicit sale and distribution of ORIGINAL OXYCONTIN to its Suspect Physicians and Suspect Pharmacies furthered that illegal conspiracy by among other things PURDUE's intentional failure to comply with the mandatory reporting obligations set forth in 21 CFR 314.80 and 21 C.F.R. 1307.71, in the 2007 Vermont Consent Judgment and in the 2007 Corporate Integrity Agreement.

91. Such failures by PURDUE constitute knowing and purposeful omissions of material information which misled the FDA, the OIG and related state public health authorities in the exercise of their duties to protect the public from harm arising from the illicit sale and distribution of Class II narcotic drugs to addicts and their suppliers. Such willful acts should constitute among other things unfair and deceptive acts or practices in violation of tit. 9 Vt. Stat. Ann. section 2453 (a). As a proximate cause thereof, PURDUE is liable to the UNITED STATES and the STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFFS under such statute for ACTUAL AND PUNITIVE DAMAGES, as follows:

A. the amount of actual and consequential damages sustained by the UNITED STATES and by the STATE OF VERMONT PLAINTIFFS for years 2002 – 2010 as a part of each government's spending on SUBSTANCE ABUSE AND ADDICTION for or on behalf of persons addicted to ORIGINAL OXYCONTIN for expenditures separate and apart from the health care services and products it paid for as a part of its MEDICAID PROGRAM. This amount, upon information and belief, exceeded the sum of $100 million per year during each year from 2002 to 2010;

B. the amount of actual damages sustained by the UNITED STATES and by the

STATE OF VERMONT for the years 2002- 2010 as a part of each government's spending for Medicaid for false claims submitted for payment by PURDUE's Suspect Physicians and Suspect Pharmacy Customers in violation of the MEDICAID MEDICAL NECESSITY STANDARDS (see paragraph 10 supra);

C. Three times the value of the consideration paid by the UNITED STATES and by the STATE OF VERMONT for false claims wrongfully submitted for payment to each such government by PURDUE's Suspect Physicians and Suspect Pharmacy Customers in violation of MEDICAID MEDICAL NECESSITY STANDARDS supra); and

D. Further, PURDUE should be required to assign to Relator for subsequent assignment by Relator to a federal or private not-for-profit university and/or research facility all of its current patents or licenses to use patents owned by third-parties that relate to its ORIGINAL FORMULATION or REPLACEMENT FORMULATION for possible construction of a tapered-dosage opioid tablet for use by health care providers in the treatment of persons now addicted to heroin and other forms of opioids.

E. reasonable attorney's fees as authorized by the statute.

COUNT SIX: REQUEST FOR DAMAGES FROM DEFENDANT DISTRIBUTORS PURSUANT TO VERMONT CONSUMER PROTECTION ACT

92. RELATOR adopts PARAGRAPHS 1 – 91 as a part of COUNT SIX.

93. At all times material between 2002 and 2010 each DEFENDANT DISTRIBUTOR actively solicited and sold and distributed for purposes of sale to physicians and pharmacies then located within the State of Vermont s vast quantities of its ORGINAL FORMULATION product after each DEFENDANT had actual knowledge that a substantial portion of such sales, particularly sales of its 80 mg tablet, were being made to Vermont

physicians whom PURDUE had earlier identified and placed on their list of Suspect Pharmacy Customers (see paragraph 41 supra). This data was contained in each DEFENDANT's INTERNAL SALES DATA and other related information which had been obtained by each DEFENDANT's sales force and from IMS Health, a third-party information and technical services company then doing business with each such DEFENDANT. From such DATA and other information. each DEFENDANT DISTRIBUTOR knew and had reason to know of the actual prescription patterns followed by each Suspect Pharmacy Customer and therefore knew and had the opportunity to determine from such DATA and other related information which of its Suspect Pharmacy Customers were then actively engaged in the illegal prescription and dispensing of ORIGINAL OXYCONTIN for purposes of illicit non-medical use and diversion to persons then addicted to opioids or their suppliers.

94. During such time each DEFENDANT DISTRIBUTOR as "registrant" knowingly and with the intent to deceive failed to disclose to the FDA, the DEA or other federal or state public health or law enforcement agencies located within the State of Vermont or elsewhere that it had actual knowledge that several hundred or more of its Suspect Pharmacy Customers were illegally prescribing the ORIGINAL FORMULATION product, particularly the 80 mg tablet, for distribution to addicts or their suppliers. This failure among other things constitutes a willful and intentional failure on the part of each such DEFENDANT to comply with the mandatory reporting obligations of 21 C.F.R. section 1301.77 (see n. 6 – 8 supra).

95. During such time each DEFENDANT DISTRIBUTOR knowingly and with the intent to deceive continued to distribute ORIGINAL FORMULATION to its Suspect Pharmacy Customers then located within the State of Vermont and throughout the United States and its territories

even though it then knew or should have known from its INTERNAL SALES DATA and other related information that a majority of such sales were paid for by Medicaid as a part of an illegal conspiracy by such Pharmacies to obtain payment by Medicaid through submission of false claims in violation of the MEDICAID MEDICAL NECESSITY STANDARDS (see paragraph 10 supra).

96. Such failures by each DEFENDANT DISTRIBUTOR constitute knowing and purposeful omissions of material information which misled the FDA, the DEA, the OIG and related state law enforcement and public health authorities in the exercise of their duties to protect the public from harm arising from the illicit sale and distribution of Class II narcotic drugs to addicts and their suppliers. Such willful acts should constitute among other things unfair and deceptive acts or practices in violation of tit. 9 Vt. Stat. Ann. section 2453 (a). As a proximate cause thereof, PURDUE and each other DEFENDANT DISTRIBUTOR is liable to the UNITED STATES and the STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFFS under such statute for ACTUAL AND PUNITIVE DAMAGES, as follows:

A. the amount of actual and consequential damages sustained by the UNITED STATES and by the STATE OF VERMONT for years 2002 – 2010 as a part of each government's spending on SUBSTANCE ABUSE AND ADDICTION for or on behalf of persons addicted to ORIGINAL OXYCONTIN for expenditures separate and apart from the health care services and products it paid for as a part of its MEDICAID PROGRAM. This amount, upon information and belief, exceeded the sum of $100 million per year during each year from 2002 to 2010;

B. the amount of actual damages sustained by the UNITED STATES and by the

STATE OF VERMONT for the years 2002- 2010 as a part of each government's spending for Medicaid for false claims submitted for payment by the SUSPECT PHARMACY CUSTOMERS in violation of the MEDICAID MEDICAL NECESSITY STANDARDS (see paragraph 10 supra); and

C. Three times the value of the consideration paid by the UNITED STATES and by the STATE OF VERMONT for false claims wrongfully submitted for payment to each such government by the SUSPECT PHARMACY CUSTOMERS in violation of such MEDICAID MEDICAL NECESSITY STANDARD), and

D. reasonable attorney's fees as authorized by the statute.

COUNT SEVEN: REQUEST FOR DAMAGES INCLUDING PUNITIVE DAMAGES FROM DEFENDANT DISTRIBUTORS BASED UPON COMMON LAW FRAUD CLAIMS OF FRAUDULENT CONCEALMENT AND WILFUL NONDISCLOSURE IN BREACH OF PURDUE'S AFFIRMATIVE DUTY TO DISCLOSE:

97. RELATOR adopts PARAGRAPHS 1 –96 as a part of COUNT SIX.

98. At all times material between 2002 and 2010 PURDUE and each DEFENDANT DISTRIBUTOR distributed for purposes of sale vast quantities of its ORGINAL FORMULATION product after it had actual knowledge that a substantial portion of such sales, particularly sales of its 80 mg tablet, were being made to physicians whom PURDUE had earlier identified and placed on their list of "Suspect Physicians (see paragraph 34 supra). This data was contained in its INTERNAL SALES DATA and other related information which had been obtained by the PURDUE sales force and from IMS Health, a third-party information and technical services company doing business with PURDUE. From such DATA PURDUE knew or had reason to know of the actual prescription patterns followed by each of its prescribing physicians and therefore knew and had the opportunity to determine from such DATA and other related information

which of its prescribing physicians were then actively engaged in the illegal prescription and dispensing of ORIGINAL OXYCONTIN for purposes of illicit non-medical use and diversion to persons then addicted to opioids or their suppliers.

99. During such time PURDUE knowingly and with the intent to deceive failed to disclose to the FDA or other federal or state public health or law enforcement agencies that it had actual knowledge that several hundred or more of its "Suspect Physicians" were "recklessly" and illegally prescribing its ORIGINAL FORMULATION product, particularly the 80 mg tablet, for distribution to addicts or their suppliers. PURDUE continued its deception even after the State of Vermont and other states obtained CONSENT JUDGEMENTS which required PURDUE to identify and report to governmental officials physicians who PURDUE and its sales force believed were engaged in "atypical patterns of prescribing" as described in the "SEVEN MANDATORY REPORTING CRITERIA" identified in the 2007 Vermont Consent Judgment (see paragraph 44 supra). This failure among other things constitutes a willful and intentional failure on the part of PURDUE to comply with the reporting and certification requirements of the Corporate Integrity Agreement it signed with OIG in 2007 (see paragraphs 34.E and 45 supra).

100. During such time PURDUE as "applicant" knowingly and with the intent to deceive failed to comply with the reporting obligations set forth in 1992 21 CFR 314.80, specifically the "frequency" of illicit abuse and distribution and resulting "serious and unexpected" adverse drug experience which increased to epidemic proportions within five years after it received approval by the FDA of NDA 20 – 553 in 1995 and NDA 20 – 553/S-056 in 1996. See paragraphs 41.C – 41.D supra.

101. During such time PURDUE knowingly and with the intent to deceive continued to sell and distribute ORIGINAL FORMULATION to its Suspect Physicians even though it then knew or should have known from its INTERNAL SALES DATA and other related information that a majority of such sales were paid for by Medicaid as a part of an illegal conspiracy by such physicians to obtain payment by Medicaid through submission of false claims in violation of the MEDICAID MEDICAL NECESSITY STANDARDS (see paragraph 10 supra).

102. PURDUE's failure to make periodic or annual reporting when due to the FDA, the State of Vermont, the Office of Inspector General and the DEA and other state and federal agencies constituted numerous and ongoing misrepresentations of material fact, which representations were known by PURDUE to be false when made. Such misrepresentations included PURDUE's failure to comply as "applicant" with 21 C.F.R. section 314.80 (see n. 3 – 4 supra) and as "registrant" with 21 C.F.R. section 1301.71 (see n. 6 – 8 supra). Such misrepresentations were relied upon by the FDA, the State of Vermont, and the Office of Inspector General. Such misrepresentations, when made, constituted willful nondisclosures in violation of PURDUE's obligation to make a full and timely report of material information in conformity to the terms of 21 CFR 314.80 and 21 C.F.R. section 1301.77, the 2007 Vermont Consent Judgment and the 2007 Corporate Integrity Agreement.

103. As a proximate result thereof, PURDUE is liable to the UNITED STATES and the STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFSS for actual and punitive damages, as follows:

A. the amount of actual and consequential damages sustained by the UNITED STATES and the STATE OF VERMONT PLAINTIFFS for the years 2002 – 2010 as a part of its spending

on SUBSTANCE ABUSE and ADDICTION, which expenditures are separate and apart from the health care services and products it paid for as a part of its MEDICAID REIMBURSEMENT PROGRAM. This amount, upon information and belief, exceeded the sum of $150 million per year during each year from 2002 to 2010;

B. the amount of actual damages sustained by the UNITED STATES and by the STATE OF VERMONT for the years 2002- 2010 for false claims submitted to for payment by PURDUE's Suspect Physicians in violation of MEDICAID MEDICAL NECESSITY STANDARDS (see paragraph 10 supra), and

C. punitive damages equal to three times the actual damages sustained by the UNITED STATES, the STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFFS during such years.

COUNT EIGHT: REQUEST FOR DAMAGES INCLUDING PUNITIVE DAMAGES BASED UPON COMMON LAW FRAUD CLAIMS OF FRAUDULENT CONCEALMENT AND WILFUL NONDISCLOSURE IN BREACH OF DEFENDANT DISTRIBUTORS' AFFIRMATIVE DUTY TO DISCLOSE:

104. RELATOR adopts PARAGRAPHS 1 – 103 as a part of COUNT SEVEN.

105. At all times material between 2002 and 2010 each DEFENDANT DISTRIBUTOR as "registrant" distributed for purposes of sale vast quantities of the ORGINAL FORMULATION product after it had actual knowledge that a substantial portion of such sales, particularly sales of its 80 mg tablet, were being made to physicians whom PURDUE had earlier identified and placed on their list of Suspect Physicians (see paragraph 36 supra). This data was contained in the INTERNAL SALES DATA and other related information which had been obtained by PURDUE and other DEFENDANT DISTRIBUTOR from IMS Health, a third-party information and technical

services company doing business with PURDUE and each other DISTRIBUTOR. From such DATA each DEFENDANT DISTRIBUTOR knew or had reason to know of the actual prescription patterns followed by each of its prescribing physician customers and therefore knew and had the opportunity to determine from such DATA and other related information which of its Suspect Pharmacy Customers were then actively engaged in the illegal prescription and dispensing of ORIGINAL OXYCONTIN for purposes of illicit non-medical use and diversion to persons then addicted to opioids or their suppliers.

106. During such time each DEFENDANT DISTRIBUTOR as "registrant" knowingly and with the intent to deceive failed to disclose to the FDA, the DEA or other federal or state public health or law enforcement agencies that it had actual knowledge that several hundred or more of its Suspect Pharmacy Customers were illegally prescribing ORIGINAL FORMULATION product, particularly the 80 mg tablet, for distribution to addicts or their suppliers.

107. Each DEFENDANT DISTRIBUTOR'S failure to make periodic or annual reporting when due to the DEA, the State of Vermont, and other state and federal agencies constituted numerous and ongoing misrepresentations of material fact, which representations were known by such DEFENDANTS to be false when made. Such misrepresentations included each such DEFENANT's failure to comply as "registrant" with 21 C.F.R. section 1301.71 (see n. 6 – 8 supra). Such misrepresentations were relied upon by the DEA and the State of Vermont. Such misrepresentations, when made, constituted willful nondisclosures in violation of PURDUE's obligation to make a full and timely report of material information in conformity to the terms of 21 CFR section 1301.77 and the 2007 Vermont Consent Judgment.

108. As a proximate result thereof, each DEFENDANT DISTRIBUTOR is liable to the

UNITED STATES and the STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFFS for actual and punitive damages, as follows:

A. the amount of actual and consequential damages sustained by the UNITED STATES and the STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFFS for the years 2002 – 2010 as a part of each PLAINTIFF's spending on SUBSTANCE ABUSE and ADDICTION, which expenditures are separate and apart from the health care services and products it paid for as a part of its MEDICAID REIMBURSEMENT PROGRAM. This amount, upon information and belief, exceeded the sum of $150 million per year during each year from 2002 to 2010;

B. the amount of actual damages sustained by the UNITED STATES and by the STATE OF VERMONT for the years 2002- 2010 for false claims submitted for payment by PURDUE's Suspect Physicians in violation of MEDICAID MEDICAL NECESSITY STANDARDS (see paragraph 10 supra), and

C. punitive damages equal to three times the actual damages sustained by the UNITED STATES, the STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFFS during such years.

WHEREFORE RELATOR ON BEHALF OF THE UNITED STATES, THE STATE OF VERMONT, and the VERMONT LOCAL GOVERNMENT PLAINTIFFS DEMAND JUDGMENT IN THEIR FAVOR AGAINST DEFENDANT PURDUE and each DEFENDANT DISTRIBUTOR for all damages and injunctive claimed in COUNTS TWO – EIGHT of this COMPLAINT and further requests a ruling in his or their favor on each issue identified in COUNT ONE (requests for declaratory judgment).

RELATOR ON BEHALF OF EACH SUCH PLAINTIFF FURTHER REQUESTS A TRIAL BY JURY IN THIS ACTION PURSUANT TO Rule 38, F.R.Civ.P.

April 19, 2018

ROBERT E. MANCHESTER, RELATOR
On behalf of the UNITED STATES, THE STATE OF VERMONT and the VERMONT LOCAL GOVERNMENT PLAINTIFFS

BY: _____

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UNITED STATES DISTRICT COURT
for the DISTRICT OF VERMONT

docket no. _____

UNITED STATES OF AMERICA et.al.
ex rel. MANCHESTER

v.

PURDUE PHARMA, L.P. et. al.

CERTIFICATE OF SERVICE

On April 20, 2018 I served a copy of the complaint and other materials identified by 31 U.S.C. section 3730 (b) (3) and 32 Vt. Stat. Ann. section 632 (b) (2) upon the following parties pursuant to F.R.Civ.P. 4 (i):

1. The Hon. Jefferson B. Sessions, United States Attorney General, by certified mail, return receipt requested pursuant to Rule 4 (i) (1) (B);

2. The Hon. Christine E. Nolan, Esq., US Attorney for District of Vermont, by certified mail, return receipt requested, pursuant to Rule 4 (i) (1) (A) (ii);

3. The Hon. T.J. Donovan, Esq., Vermont Attorney General, by certified mail, return receipt requested, pursuant to Rule 4 (j) ((2) (B). See V.R.Civ.P. 4 (d) (2), Reporter's Notes to 2016 Amendment.

Francis G. Conrad, Esq.